

NATIONAL QUALITY FORUM

RENAL ENDORSEMENT MAINTENANCE STEERING COMMITTEE

Conference Call October 13, 2011, 1:00pm – 3:00pm ET

Committee Members Present: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Constance Anderson, BSN, MBA; Jeffrey Berns, MD; Lorien Dalrymple, MD, MPH; Andrew Fenves, MD; Michael Fischer, MD, MSPH; Jerry Jackson, MD; Rick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Alan Kliger, MD; Lisa Latts, MD, MSPH, MBA; Kathe LeBeau; Joseph Nally, MD; Andrew Narva, MD; Jessie Pavlinac, MS, RD; Michael Somers, MD; Ruben Velez, MD; Harvey Wells.

NQF Staff Present: Karen Pace, PhD, RN, Senior Program Director.

Others Present: Amy Beckrich, Thomas Dudley, Diedra Joseph, Lisa McGonigal, Joe Messana, Robyn Nishimi, Dale Singer, Jennifer Stone, Robert Wolfe.

The full transcripts and audio recordings from the meeting can be found [here](#).

MEETING PROCESS

Dr. Crook and Dr. Schonder (Co-Chairs) welcomed the Steering Committee members and thanked them for their continued participation.

The purpose of the call was to:

- review the measures evaluated by the workgroups (particularly those where differences of opinion persist) to prepare for full Steering Committee voting (after the call);
- review follow-up information on measures evaluated at the meeting and determine if further action indicated; and
- introduce measures that require further evaluation.

NQF staff briefly introduced the measures including a description of the outcome of the workgroup discussions and any re-voting. The Steering Committee was encouraged to seek any clarifications or rationale to prepare for voting on the measures after the call. A NQF member and public comment period occurred at the end of the call.

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EVALUATION OF RENAL MEASURES

The following tables compile a summary of the workgroup’s discussion and ratings and comments from re-voting, if indicated.

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| 0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose |
| <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>9/20 Workgroup Call Summary</p> <p>The following summarizes the workgroup’s discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report</p> <p>1a. Impact – Preliminary ratings indicated agreement that high impact was met.</p> <p>1b. Performance Gap – Preliminary ratings indicated agreement that there is a performance gap (1st quartile-67%; median-79%; 3rd quartile-88%).</p> <p>1c. Evidence – 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 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. The developer</p> |

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| 0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose |
| <p>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 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. 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 (8-13% higher risk of mortality).</p> <p>3. Usability – This measure is probably not needed - should be incorporated into adequacy measure.</p> <p>4. Feasibility – The preliminary evaluations indicated no issues with feasibility.</p> <p>5. Suitable for endorsement – The preliminary evaluations were divided and the Workgroup will re-vote on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks**)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): Yes 1a. Impact: H-5; M-1; L-0; I-0 1b. Performance Gap: H-2; M-4; L-0; I-0 Rationale: All are important measures with high impact and demonstrated performance gaps.</p> <p>1c. Evidence (based on decision logic): Yes Quantity: H-1; M-5; L-0; I-0 Quality: H-1; M-4; L-1; I-0 Consistency: H-1; M-5; L-0; I-0 Rationale: Evidence does not address the need to measure adequacy on a monthly basis, as outlined in the measure. **0247 and 253: while there is correlation between SMR and monthly measurement of delivered dose, it is unclear that the interval of measurement - monthly - - was tested as critical to these measures. Might every other month measure or every 3 month measurement accomplish the same end? The body of evidence does not address this - - and these measures focus on frequency of measurement.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): Yes 2a. Reliability: H-4; M-2; L-0; I-0 2b. Validity: H-3; M-3; L-0; I-0 Rationale: Good reliability and validity reported.</p> <p>3. Usability: H-5; M-1; L-0; I-0 Rationale: All measures demonstrate high usability and feasibility</p> <p>4. Feasibility: H-6; M-0; L-0; I-0 Rationale: All measures demonstrate high usability and feasibility</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-6; N-0 Rationale: Would recommend moving toward weekly standardized Kt/V measurements for measures to account for different frequencies dialysis sessions. **For 0247 and 0248, agree with committee discussion that harmonization of these HD adequacy measures needed. Similarly, there should be harmonization of the PD adequacy measures. 0247 and 0248 should be consolidated into a single metric with 0249. 0249 can be revised to include patients who have the favored method of measurement and can be written to provide a low result for facilities not performing kt/V.</p> |
| <p>If applicable, Conditions/Questions for Developer: Have 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, 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</p> |

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| 0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose |
| 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. |
| Steering Committee Follow-up: |
| 10/13 Steering Committee Conference Call |
| 1.Importance to Measure and Report The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0249). 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. The Steering Committee will vote on whether it agrees that this measure is not needed. |
| 2. Scientific Acceptability of Measure Properties |
| 3. Usability |
| 4. Feasibility |

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| 0248 Hemodialysis Adequacy Clinical Performance Measure II: Method of Measurement of Delivered Hemodialysis Dose |
| <p>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.</p> <p>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.</p> <p>Denominator Statement: Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. This measure is not stratified.</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>9/20 Workgroup Call Summary</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report</p> <p>1a. Impact – Preliminary ratings indicated agreement that high impact was met.</p> <p>1b. Performance Gap – The performance gap (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.</p> <p>1c. Evidence - The evidence is indirect – it's about dialysis adequacy, not frequency of measurement. Assessment is necessary but not sufficient to achieving adequate dialysis. No evidence supporting one method over another. The validity testing presented demonstrates some relationship to SMR. Daugirdas II also can be used with standard Kt/V and different frequencies as long as the pre-dialysis interval is known. 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</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 (0.96) to distinguish among facilities.</p> <p>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).</p> <p>3. Usability – This measure is probably not needed - should be incorporated into adequacy measure.</p> <p>4. Feasibility – The preliminary evaluations indicated no issues with feasibility.</p> <p>5. Suitable for endorsement – The preliminary evaluations were divided and the Workgroup will re-vote on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks**)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-6; M-0; L-0; I-0</u> 1b. Performance Gap: <u>H-1; M-3; L-1; I-1</u></p> <p>Rationale: All are important measures with high impact and demonstrated performance gaps. **Because the metric is incorrectly specified, the performance gap is irrelevant to the intention of the metric - that a specific method of measurement be used. **For both 0248 and 0254, the numerator is a composite of 2 outcomes: if a measurement was made, and the method of calculating that measurement. In each case, it is unclear whether the performance gap represents non-collection of the clearance, or using a method other than the measure-recommended method. Both measures purport to measure the method of measurement, but do not do so - - confounded by whether or not any measurement was made.</p> <p>Rationale: 1c. Evidence (based on decision logic): <u>Yes</u></p> <p>Quantity: <u>H-0; M-5; L-1; I-0</u> Quality: <u>H-1; M-4; L-1; I-0</u> Consistency: <u>H-0; M-5; L-0; I-1</u></p> <p>Rationale: Indirect evidence provided for measure (evidence of kinetic modeling to health outcomes, but not the specific method of measurement)</p> |
| <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u></p> <p>2a. Reliability: <u>H-4; M-1; L-1; I-0</u> 2b. Validity: <u>H-3; M-3; L-0; I-0</u></p> |

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| <p>0248 Hemodialysis Adequacy Clinical Performance Measure II: Method of Measurement of Delivered Hemodialysis Dose</p> <p>Rationale: Good reliability and validity reported, although validity does not show benefit of Daugirdas II. **The measure is incorrectly specified - it does not do what its name says. 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.</p> <p>3. Usability: H-5; M-0; L-0; I-1</p> <p>Rationale: All measures demonstrate high usability and feasibility. **Because the metric does not measure what the name of the metric says, it is not useful.</p> <p>4. Feasibility: H-6; M-0; L-0; I-0</p> <p>Rationale: All measures demonstrate high usability and feasibility.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-5; N-1</p> <p>Rationale: Would recommend moving toward weekly standardized Kt/V measurements for measures to account for different frequencies dialysis sessions. **For 0247 and 0248, agree with committee discussion that harmonization of these HD adequacy measures needed. Similarly, there should be harmonization of the PD adequacy measures. **0247 and 0248 should be consolidated into a single metric with 0249. 0249 can be revised to include patients who have the favored method of measurement and can be written to provide a low result for facilities not performing kt/V.</p> <p>If applicable, Conditions/Questions for Developer: Have 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.</p> <p>Developer Response: The 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> <p>Steering Committee Follow-up:</p> |
| <p>10/13 Steering Committee Conference Call</p> <p>1. Importance to Measure and Report</p> <p>The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0249). 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. The Steering Committee will vote on whether it agrees that this measure is not needed.</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>3. Usability</p> <p>4. Feasibility</p> |

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| <p>0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum</p> |
| <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>9/20 Workgroup Call Summary</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report</p> <p>1a. Impact – Preliminary ratings indicated agreement that high impact was met.</p> <p>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 – 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</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 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.</p> <p>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 – The preliminary evaluations indicated no issues with usability.</p> <p>4. Feasibility – The preliminary evaluations indicated no issues with feasibility.</p> <p>5. Suitable for endorsement – The preliminary evaluations were divided primarily due to the issues discussed under scientific acceptability and the Workgroup will re-vote on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks**)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-6; M-0; L-0; I-0</u> 1b. Performance Gap: <u>H-4; M-2; L-0; I-0</u></p> <p>Rationale: All are important measures with high impact and demonstrated performance gaps.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u></p> <p>Quantity: <u>H-0; M-6; L-0; I-0</u> Quality: <u>H-0; M-6; L-0; I-0</u> Consistency: <u>H-1; M-5; L-0; I-0</u></p> <p>Rationale: Evidence same as original endorsement (KDOQI). **The evidence presented does not bear on the method of measurement</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u></p> <p>2a. Reliability: <u>H-2; M-2; L-2; I-0</u> 2b. Validity: <u>H-2; M-2; L-2; I-0</u></p> <p>Rationale: Reliability and validity are adequate, given low numbers of PD patients - difficult to show tight statistics. **Developer indicates that repeated measurements show value of measure. **All peritoneal dialysis measures: Low numbers of patients in each dialysis facility</p> |

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| <p>0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum</p> <p>rendered reliability and validity testing inadequate. There were large confidence intervals, and while signal to noise analyses gave significant findings in the aggregate, there were large confidence intervals in analyses by facility.</p> <p>3. Usability: H-4; M-2; L-0; I-0 Rationale: All measures demonstrate high usability and feasibility.</p> <p>4. Feasibility: H-5; M-1; L-0; I-0 Rationale: All measures demonstrate high usability and feasibility.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-5; N-1 Rationale: 0318, 0253 and 0254: The three CMS PD metrics should be combined into a single metric - it can be constructed such that to make the numerator the Kt/V must be done and must be done with the approved method.</p> <p>If applicable, Conditions/Questions for Developer: Have 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, 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> <p>Steering Committee Follow-up:</p> <p>10/13 Steering Committee Conference Call</p> <p>1.Importance to Measure and Report</p> <p>2. Scientific Acceptability of Measure Properties The workgroup differed in its assessment of reliability and validity. Although appropriate testing was conducted, the results were not strong (Interunit Reliability was 0.57; validity testing results indicated that performance on this measure is not associated with performance on standardized mortality ratio. The developer and some committee members thought these results were due to small case volume and wide confidence intervals. This measure is an intermediate outcome measure of dialysis adequacy and preferred over simply the frequency or method of assessing adequacy.</p> <p>3. Usability</p> <p>4. Feasibility</p> |
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| 0253 Peritoneal Dialysis Adequacy Clinical Performance Measure I - Measurement of Total Solute Clearance at Regular Intervals |
| <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>9/20 Workgroup Call Summary</p> <p>1.Importance to Measure and Report</p> <p>1a. Impact – Preliminary ratings indicated agreement that high impact was met.</p> <p>1b. Performance Gap – Preliminary ratings indicated agreement that there is a performance gap (1st quartile-0%; median-50%; 3rd quartile-80%).</p> <p>1c. Evidence – The evidence is indirect – it's about dialysis adequacy, not frequency of measurement. 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</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).</p> <p>3. Usability – This measure is probably not needed - should be incorporated into adequacy measure.</p> <p>4. Feasibility – The preliminary evaluations indicated no issues with feasibility.</p> <p>5. Suitable for endorsement – The preliminary evaluations were divided and the Workgroup will re-vote on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks**)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-6; M-0; L-0; I-0</u> 1b. Performance Gap: <u>H-6; M-0; L-0; I-0</u></p> <p>Rationale:</p> <p>1c. Evidence (based on decision logic): <u>Yes</u></p> <p>Quantity: <u>H-1; M-5; L-0; I-0</u> Quality: <u>H-0; M-5; L-1; I-0</u> Consistency: <u>H-0; M-6; L-0; I-0</u></p> <p>Rationale: Indirect evidence provided (addresses association of adequacy with mortality, but does not address frequency of measurement with outcomes). **0247 and 253: while there is correlation between SMR and monthly measurement of delivered dose, it is unclear that the interval of measurement - monthly - - was tested as critical to these measures. Might every other month measure, or every 3 month measurement accomplish the same end? The body of evidence does not address this - - and these measures focus on frequency of measurement.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>No</u></p> <p>2a. Reliability: <u>H-1; M-4; L-1; I-0</u> 2b. Validity: <u>H-2; M-2; L-1; I-0</u></p> <p>Rationale: Reliability and validity are adequate given low number of PD patients (same issues for all PD measures - wide distribution due to low #). **All peritoneal dialysis measures: Low numbers of patients in each dialysis facility rendered reliability and validity testing inadequate. There were large confidence intervals, and while signal to noise analyses gave significant findings in the aggregate, there were large confidence intervals in analyses by facility.</p> |

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| 0253 Peritoneal Dialysis Adequacy Clinical Performance Measure I - Measurement of Total Solute Clearance at Regular Intervals |
| 3. Usability: H-5; M-1; L-0; I-0 Rationale: All measures demonstrate high usability and feasibility. |
| 4. Feasibility: H-5; M-1; L-0; I-0 Rationale: All measures demonstrate high usability and feasibility. |
| Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-5; N-1 Rationale: 0318, 0253 and 0254: The three CMS PD metrics should be combined into a single metric - it can be constructed such that to make the numerator the Kt/V must be done and must be done with the approved method. |
| If applicable, Conditions/Questions for Developer: Have 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, 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. |
| Steering Committee Follow-up: |
| 10/13 Steering Committee Conference Call |
| 1.Importance to Measure and Report The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0318). CMS decided that 0249 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. The Steering Committee will vote on whether it agrees that this measure is not needed. |
| 2. Scientific Acceptability of Measure Properties |
| 3. Usability |
| 4. Feasibility |

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| <p>0254 Peritoneal Dialysis Adequacy Clinical Performance Measure II - Calculate Weekly Kt/Vurea in the Standard Way</p> <p>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.</p> <p>Numerator Statement: Patients with:</p> <ul style="list-style-type: none">(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. <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>9/20 Workgroup Call Summary</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report</p> <ul style="list-style-type: none">1a. Impact – Preliminary ratings indicated agreement that high impact was met.1b. Performance Gap – The performance gap 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 (1st quartile-0%; median-33%; 3rd quartile-57%).1c. Evidence - The evidence is indirect – it's about dialysis adequacy, not frequency of measurement. 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>2. Scientific Acceptability of Measure Properties</p> <ul style="list-style-type: none">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). <p>3. Usability – This measure is probably not needed - should be incorporated into adequacy measure.</p> <p>4. Feasibility – The preliminary evaluations indicated no issues with feasibility.</p> <p>5. Suitable for endorsement – The preliminary evaluations were divided and the Workgroup will re-vote on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks**)</p> <p>1. Importance to Measure and Report (based on decision logic): <u>No</u></p> <p>1a. Impact: <u>H-5; M-1; L-1; I-0</u> 1b. Performance Gap: <u>H-2; M-2; L1-; I-1</u></p> <p>Rationale: All are important measures with high impact and demonstrated performance gaps. **Performance gap includes all patients (HD and PD) - unsure of true performance gap. **Same problem as 0248: Not specified properly so does not measure what the name of the metric states it is measuring. Thus the performance gap data does not support the title of the metric. **For both 0248 and 0254, the numerator is a composite of 2 outcomes: if a measurement was made, and the method of calculating that measurement. In each case, it is unclear whether the performance gap represents non-collection of the clearance, or using a method other than the measure-recommended method. Both measures purport to measure the method of measurement, but do not do so - - confounded by whether or not any measurement was made.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u></p> <p>Quantity: <u>H-0; M-5; L-1; I-0</u> Quality: <u>H-0; M-5; L-1; I-0</u> Consistency: <u>H-0; M-6; L-0; I-0</u></p> <p>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.</p> |

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| 0254 Peritoneal Dialysis Adequacy Clinical Performance Measure II - Calculate Weekly KT/Vurea in the Standard Way |
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| <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: <u>H-0; M-4; L-2; I-0</u> 2b. Validity: <u>H-0; M-4; L-2; I-0</u> Rationale: Reliability and validity are adequate given low number of PD patients (same issues for all PD measures - wide distribution due to low #). **Same as 0248 - the metric is incorrectly specified so does not measure what the name of the metric suggest - the percentage of patients who have their Kt/V measured in the best fashion. **All peritoneal dialysis measures: Low numbers of patients in each dialysis facility rendered reliability and validity testing inadequate. There were large confidence intervals, and while signal to noise analyses gave significant findings in the aggregate, there were large confidence intervals in analyses by facility.</p> |
| <p>3. Usability: <u>H-3; M-2; L-1; I-0</u> Rationale: All measures demonstrate high usability and feasibility. Not useful as it does not measure what its name says.</p> |
| <p>4. Feasibility: <u>H-5; M-1; L-0; I-0</u> Rationale: All measures demonstrate high usability and feasibility</p> |
| <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-3; N-3</u> Rationale: 0318, 0253 and 0254: The three CMS PD metrics should be combined into a single metric - it can be constructed such that to make the numerator the Kt/V must be done and must be done with the approved method.</p> |
| <p>If applicable, Conditions/Questions for Developer: Have 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, 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> |
| <p>Steering Committee Follow-up: 10/13 Steering Committee Conference Call 1.Importance to Measure and Report The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0318). 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 (0318) is endorsed, this measure is not needed. The Steering Committee will vote on whether it agrees that this measure is not needed. 2. Scientific Acceptability of Measure Properties 3. Usability 4. Feasibility</p> |

Recommendations Regarding Future Measures of Dialysis Adequacy

- Weekly std 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 be encouraged to consider using other metrics for dialysis adequacy: patient volume expansion, time, ultrafiltration rate, Kt, QoL measures all are possible candidates. Urea kinetic modeling is not the only, or perhaps not even the best, measure of dialysis adequacy.

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- Dialysis adequacy measures should be harmonized across the facility and the physician level of assessment.

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| 0255 Measurement of Serum Phosphorus Concentration |
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| <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>9/19 Workgroup Call Summary (In attendance: Peter Crooks(Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report</p> <p>1a. Impact – See discussion of high impact under overarching issues. After discussion, the workgroup agreed that mineral metabolism was a high impact aspect of healthcare for dialysis patients.</p> <p>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 – The preliminary ratings were spread across all the categories. 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, because the evidence does not support a measure of a specific phosphorus value (also noted by KDIGO), some Committee members were concerned misinterpretation of the importance if no measure related to serum phosphorus was recommended. 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.</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>The preliminary ratings were spread across all the rating categories.</p> <p>2a. Reliability The preliminary reliability ratings were mixed, but CMS did submit additional reliability testing that indicate the interunit reliability was 0.94.</p> <p>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 - The preliminary ratings were spread across all the rating categories. Because of the limitations already noted under evidence, some Committee members did not think this measure would be that useful for evaluating quality.</p> <p>4. Feasibility - Preliminary ratings indicated agreement that feasibility was met. One member just noted that phosphorus is measurable and should be relatively easy to get.</p> <p>5. Suitable for endorsement - The preliminary ratings were spread across all the rating categories.</p> <p>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. Another member noted that the absence of RCTs and interventional trials would not support this as a performance measure. There was also concern that a monthly measurement is not necessary. However, another member noted that the absence of RCTs does not mean it shouldn't be endorsed as a performance measure. There is some evidence that is important. And for phosphorus, the correlative data to survival is so remarkably strong that it is important enough to be a performance measure. The Workgroup will revote on this measure.</p> |

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| 0255 Measurement of Serum Phosphorus Concentration |
| The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks) |
| <p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u> 1a. Impact: <u>H-7; M-1; L-1; I-0</u> 1b. Performance Gap: <u>H-0; M-4; L-4; I-1</u> Rationale: Data regarding performance gap did not seem to show a substantial one. **Observational studies suggest that elevation of serum phosphorus and advanced CKD is associated with increased risk of mortality. **Unfortunately, we do not have good evidence for randomized control trials that effective therapy reduces risk. Nevertheless, measurement of Phos in CKD appears reasonable. This same statements cannot be applied to monitoring serum calcium or PTH in CKD. **Major concern about PMs on just measuring a lab test. Need for monthly testing of phos and calcium in ESRD not evidence based and need for testing varies with active treatment regimen. **Rated as High Impact because measurement of Serum Phos is important due to clinical consequences associated with serum Phos level. **Performance gap low as monthly testing is paid for and monthly labs are routine in the vast majority of facilities.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> Quantity: <u>H-3; M-6; L-0; I-0</u> Quality: <u>H-0; M-6; L-3; I-0</u> Consistency: <u>H-3; M-4; L-2; I-0</u> Rationale: Studies are generally cross-sectional or observational. **Little data (and no RCTs) on intervention and actual outcome. In general lots of studies which in the end point to association mostly with phos and CVD outcomes, much less if any such association independently with PTH/calcium. We remain without data to support frequency of monitoring or impact on treatment. **Evidence provided supports measurement of Phos, but not at monthly interval suggested. **The evidence for all of these measures fails to clearly link the process with an outcome, but there is a very strong association between mortality and phosphorus level in dialysis patients (0255), and expert agreement that high phosphorus levels should be treated.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u> 2a. Reliability: <u>H-5; M-3; L-1; I-0</u> 2b. Validity: <u>H-3; M-5; L-1; I-0</u> Rationale: Reliability testing presented (correlations over time) is not really testing reliability; validity testing is OK but I have concerns about the 1 month time interval? Why should these parameters be checked each month. I realize that is what is currently done but there is no data to support is validity. **Reliability and Validity testing adequate for measure already in use.</p> <p>3. Usability: <u>H-6; M-1; L-2; I-0</u> Rationale:</p> <p>4. Feasibility: <u>H-7; M-2; L-0; I-0</u> Rationale: Concerns regarding how meaningful or understandable 255 would be as a quality measure. **Measure is already in place.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-6; N-2</u> Rationale: My main issue with 0255 relates to the 1 month time interval and the fact that these are process measures with less linkage to hard outcomes. **I find it difficult to endorse 255 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 Phos is important due to clinical consequences. In absence of a meaningful measure that associates outcomes, this process measure is in line with good quality care. Would recommend decreasing measurement interval to quarterly. **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>If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up:</p> |
| <p>10/13 Steering Committee Conference Call 1.Importance to Measure and Report 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. 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 3. Usability</p> |

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| 0255 Measurement of Serum Phosphorus Concentration |
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| 4. Feasibility |
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| 0261 Measurement of Serum Calcium Concentration |
| <p>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</p> <p>Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum calcium 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, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p> |
| <p>9/19 Workgroup Call Summary (In attendance: Peter Crooks(Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup’s discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report –</p> <p>1a. Impact- The preliminary ratings were spread across all the rating categories. See discussion of high impact under overarching issues. After discussion, the workgroup agreed that mineral metabolism was a high impact aspect of healthcare for dialysis patients.</p> <p>1b. Performance Gap- The preliminary ratings were low to moderate. The mean performance rate was also 77% of this measure (as with the phosphorus assessment measure).</p> <p>1c. Evidence – The preliminary ratings mostly indicated that the evidence criteria were not met. 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. 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. Another Committee member noted that the data are far less convincing for that of calcium vs. phosphorus. 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 (#) 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. This recommendation was forwarded to the measure developer for consideration.</p> <p>.</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>The preliminary ratings were spread across all the rating categories.</p> <p>2a. Reliability – The preliminary reliability ratings were mixed, but CMS did submit additional reliability testing that indicate the interunit reliability was 0.94.</p> <p>and 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.</p> <p>3. Usability - The preliminary ratings were spread across all the rating categories.</p> <p>One member noted that the measure was understandable but not useful or meaningful. The measure of hypercalcemia is more useful.</p> <p>4. Feasibility - Preliminary ratings indicated agreement that feasibility was met.</p> <p>5. Suitable for endorsement - The preliminary ratings were spread across all the rating categories.</p> <p>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.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (<i>comments separated by asterisks</i>)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: <u>H-2; M-4; L-3; I-0</u> 1b. Performance Gap: <u>H-0; M-4; L-4; I-1</u></p> <p>Rationale:</p> <p>1c. Evidence (based on decision logic): No</p> |

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| 0261 Measurement of Serum Calcium Concentration |
| <p>Quantity: <u>H-2; M-5; L-2; I-0</u> Quality: <u>H-0; M-5; L-4; I-0</u> Consistency: <u>H-0; M-5; L-4; I-0</u></p> <p>Rationale: Studies are generally cross-sectional or observational. **Little data (and no RCTs) on intervention and actual outcome. For 574 and 571, no data on frequency of assessment affecting outcome, especially across spectrum of CKD proposed. **In general lots of studies which in the end point to association mostly with phos and CVD outcomes, much less if any such association independently with PTH/calcium. We remain without data to support frequency of monitoring or impact on treatment. **Evidence provided supports measurement of calcium in relation to Phos and PTH, but does not support monthly interval suggested. **The evidence for all of these measures fails to clearly link the process with an outcome, but there is a very strong association between mortality and phosphorus level in dialysis patients (0255), and expert agreement that high phosphorus levels should be treated.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u></p> <p>2a. Reliability: <u>H-5; M-2; L-2; I-0</u> 2b. Validity: <u>H-3; M-4; L-1; I-1</u></p> <p>Rationale: Reliability testing presented (correlations over time) is not really testing reliability; validity testing is OK but I have concerns about the 1 month time interval? Why should these parameters be checked each month. I realize that is what is currently done but there is no data to support its validity. ** Reliability and Validity testing adequate for measure already in use.</p> <p>3. Usability: <u>H-4; M-3; L-2; I-0</u></p> <p>Rationale: Concerns regarding how meaningful or understandable 261 would be as a quality measure. **Measure already in place.</p> <p>4. Feasibility: <u>H-6; M-2; L-1; I-0</u></p> <p>Rationale:</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-5; N-3</u></p> <p>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 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.</p> <p>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.</p> <p>Developer Response: The 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> <p>Steering Committee Follow-up:</p> |
| <p>10/13 Steering Committee Conference Call</p> <p>1.Importance to Measure and Report</p> <p>The Workgroup recommended this measure be incorporated into the intermediate outcome endorsed measure for hypercalcemia (1454). 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. The Steering Committee will vote on whether it agrees that this measure is not needed.</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>3. Usability</p> <p>4. Feasibility</p> |

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| 0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH) |
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| <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>9/19 Workgroup Call Summary (In attendance: Peter Crooks(Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup’s discussion and subsequent action (if any) for this measure: There were some initial concerns expressed with how CKD was defined by the measure developer. The developer clarified that the measure only includes CKD stage 3 and above and excludes dialysis.</p> <p>1.Importance to Measure and Report –</p> <p>1a. Impact- The preliminary ratings were spread across all the rating categories. See discussion on high impact in overarching issues. Given, the lack of evidence, the Committee members did not think this should be considered high impact.</p> <p>1b. Performance Gap- The preliminary ratings were spread across all the rating categories. 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 – The preliminary ratings and comments indicated that the criteria for evidence were not met. The evidence does not support a measure that suggests PTH should be assessed annually in patients with CKD state 3.</p> <p>2. Scientific Acceptability of Measure Properties The preliminary ratings were spread across all the rating categories. Same concerns as in 0570 about the reliability and validity testing</p> <p>2a. Reliability 2b. Validity.</p> <p>3. Usability - The preliminary ratings were spread across all the rating categories. Same concerns as in 0570 and 0574.</p> <p>4. Feasibility - The preliminary ratings were spread across all the rating categories. Same concerns as in 0570 and 0574.</p> <p>5. Suitable for endorsement - The workgroup agreed that the criteria for suitability for endorsement were not met. The Workgroup will revote on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-1; M-1; L-7; I-0 1b. Performance Gap: H-2; M-4; L-3; I-0</p> <p>Rationale: 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 risks associated with PTH not as relevant to early stages of CKD and routine monitoring may negatively impact QOL for unnecessary test. ** Impact is low as there is insufficient evidence linking this to better outcomes. This does make more clinical sense than an annual measure of calcium, but most CKD Stage 3 patients are stable and do not really require this.</p> <p>1c. Evidence (based on decision logic): No</p> <p>Quantity: H-1; M-3; L-5; I-0 Quality: H-0; M-2; L-6;- I-1 Consistency: H-0; M-3; L-5; I-1</p> <p>Rationale: Few studies cited, study designs are generally cross-sectional, results are highly variable. ** No data on frequency of assessment affecting outcome, especially across spectrum of CKD proposed. ** The measurement of these elements in patients with</p> |

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| 0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH) |
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| <p>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. ** In general lots of studies which in the end point to association mostly with phos and CVD outcomes, much less if any such association independently with PTH/calcium. We remain without data to support frequency of monitoring or impact on treatment. ** Evidence provided is primarily from clinical practice guidelines - no evidence provided to demonstrate improvement in patient outcomes associated with this measure. ** The evidence for all of these measures fails to clearly link the process with an outcome, but there is a very strong association between mortality and phosphorus level in dialysis patients (0255), and expert agreement that high phosphorus levels should be treated.</p> |
| <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>No</u> 2a. Reliability: H-0; M-1; L-5; I-2 2b. Validity: H-0; M-0; L-6; I-2 Rationale: Not sure how changes over time demonstrate reliability. I have major concerns about validity because of the codes used to define CKD - there appear to be errors with the codes (e.g., eGFR > 60) and no explanation is provided as to why a certain number of codes are needed to define the CKD cohort. Errors here could result in misclassification and compromise validity. **Concerns regarding denominator definition and ability to get reliable data. **Reliability and Validity testing do not appear to be appropriate. **Want to withhold evaluating 574 and 571 as the information we requested from the developers on measure 570 should also apply here.</p> |
| <p>3. Usability: H-0; M-3; L-5; I-1 Rationale: 0571 and 0574 - unclear to me how easy it will be to obtain these data on CKD patients. **With 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.</p> |
| <p>4. Feasibility: H-1; M-1; L-5; I-2 Rationale: Appears to be very complex measure and may not be feasible for most groups. ** 0574 & 0571: 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: Y-0; N-8 Rationale: I think that 0574 and 0571 have more serious problems as outlined earlier - validity of definitions, feasibility, limited hard data in CKD, etc. **Although measurement of calcium and PTH are recommended for CKD patients in clinical guidelines, I do not believe the data support a performance measure for these 2 elements from NQF. 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. **Same concerns as 0574.</p> |
| <p>Given the observational studies regarding the fact of an elevated serum phosphorus in CKD on outcomes such as mortality and bone disease, I feel that measurement of serum phos is reasonable----even though we don't have good data from randomized control trials that effective treatment of hyperphosphatemia improves outcome. **I applaud IMS for developing measures for earlier stages of CKD. While these measures appear to fall a little short, the group is novel in their thinking and should continue to explore other, more concrete measures of CKD progression, as suggested in the workgroup meeting (SCr and proteinuria).</p> |
| <p>If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up:</p> |
| <p>10/13 Steering Committee Conference Call 1.Importance to Measure and Report The majority of the workgroup did not think the measure passed the evidence criterion. The evidence does not support a measure of annual PTH levels for millions of stage 3 CKD patients – what is the relationship to outcomes? 2. Scientific Acceptability of Measure Properties The majority of the workgroup did not think the measure met the criteria for reliability and validity testing. Under reliability testing, rates were given for two plans for two years. Under validity testing, rates for 5 plans and the literature were provided. The measure is proposed for clinician level performance. 3. Usability 4. Feasibility</p> |

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| 0574 CHRONIC KIDNEY DISEASE (CKD): MONITORING CALCIUM |
| <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>9/19 Workgroup Call Summary (In attendance: Peter Crooks(Co-Chair); Kristine Schonder (Co-Chair); Jeffrey Berns; Michael Fischer; Alan Kliger; Lisa Latts; Joseph Nally; Andrew Narva, MD (ex officio); Jessie Pavlinac; Michael Somers; Roberta Wager)</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>There were some initial concerns expressed with how CKD was defined by the measure developer. The developer clarified that the measure only includes CKD stage 3 and above and excludes dialysis.</p> <p>1.Importance to Measure and Report –</p> <p>1a. Impact- The preliminary ratings were spread across all the rating categories. See discussion of high impact in overarching issues.</p> <p>1b. Performance Gap- The preliminary ratings were generally low. 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 – The preliminary ratings and comments indicated that the criteria for evidence were not met. It was echoed that the evidence is just not there to support this performance measure of yearly assessment in CKD patients. One member noted that 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.</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>The preliminary ratings were spread across all the rating categories. Same concerns as in 0570 about the reliability and validity testing</p> <p>2a. Reliability -</p> <p>2b. Validity –One member expressed concern with use of the appropriate inpatient and outpatient codes. He questioned if the measure appropriately identifies individuals with CKD. The developer confirmed that the measure includes CKD stage 3 and above.</p> <p>3. Usability - The preliminary ratings were spread across all the rating categories.</p> <p>4. Feasibility - The preliminary ratings indicated agreement that the criterion of feasibility was met.</p> <p>5. Suitable for endorsement - The preliminary ratings and comments indicated that the criteria for suitability for endorsement were not met. The Workgroup will revoke on this measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-1; M-1; L-7; I-0 1b. Performance Gap: H-1; M-3; L-5; I-0</p> <p>Rationale: 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 risks associated with serum Ca not as relevant to early stages of CKD. ** Impact is low as there is insufficient evidence linking this to better outcomes and clinicians know that 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>1c. Evidence (based on decision logic): No</p> <p>Quantity: H-0; M-2; L-7; I-0 Quality: H-0; M-0; L-9-; I-0 Consistency: H-0; M-3; L-5; I-0</p> <p>Rationale: Few studies cited, study designs are generally cross-sectional, results are highly variable. **No data on frequency of</p> |

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| <p>0574 CHRONIC KIDNEY DISEASE (CKD): MONITORING CALCIUM</p> <p>assessment affecting outcome, especially across spectrum of CKD proposed. ** 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. ** In general lots of studies which in the end point to association mostly with phos and CVD outcomes, much less if any such association independently with PTH/calcium. We remain without data to support frequency of monitoring or impact on treatment. ** Evidence provided is primarily from clinical practice guidelines - little evidence to suggest importance of routine monitoring of calcium in this population. ** The evidence for all of these measures fails to clearly link the process with an outcome, but there is a very strong association between mortality and phosphorus level in dialysis patients (0255), and expert agreement that high phosphorus levels should be treated.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>No</u> 2a. Reliability: <u>H-1; M-1; L-4; I-2</u> 2b. Validity: <u>H-0; M-1; L-5; I-2</u> Rationale: Not sure how changes over time demonstrate reliability. I have major concerns about validity because of the codes used to define CKD - there appear to be errors with the codes (e.g., eGFR > 60) and no explanation is provided as to why a certain number of codes are needed to define the CKD cohort. Errors here could result in misclassification and compromise validity. **Concern re: ICD coding to retrieve data. **Reliability and Validity testing do not appear to be appropriate. **Want to withhold evaluating 574 and 571 as the information we requested from the developers on measure 570 should also apply here.</p> <p>3. Usability: <u>H-0; M-5; L-4; I-0</u> Rationale: 0571 and 0574 - unclear to me how easy it will be to obtain these data on CKD patients. **With 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.</p> <p>4. Feasibility: <u>H-1; M-1; L-6; I-1</u> Rationale: Appears to be very complex measure and may not be feasible for most groups. ** 0574 & 0571: 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: <u>Y-0; N-8</u> Rationale: I think that 0574 and 0571 have more serious problems as outlined earlier - validity of definitions, feasibility, limited hard data in CKD, etc. **Although measurement of calcium and PTH are recommended for CKD patients in clinical guidelines, I do not believe the data support a performance measure for these 2 elements from NQF. **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.</p> <p>Given the observational studies regarding the fact of an elevated serum phosphorus in CKD on outcomes such as mortality and bone disease, I feel that measurement of serum phos is reasonable----even though we don't have good data from randomized control trials that effective treatment of hyperphosphatemia improves outcome. **I applaud IMS for developing measures for earlier stages of CKD. While these measures appear to fall a little short, the group is novel in their thinking and should continue to explore other, more concrete measures of CKD progression, as suggested in the workgroup meeting (SCr and proteinuria).</p> <p>If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up:</p> <p>10/13 Steering Committee Conference Call 1.Importance to Measure and Report The majority of workgroup members did not think the measure passed impact, performance gap, or evidence, especially with including CKD Stage 3. 2. Scientific Acceptability of Measure Properties The majority of workgroup members did not think the measure passed reliability and validity. 3. Usability 4. Feasibility</p> |
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| 0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access |
| <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>The following preliminary evaluation ratings and comments are from the Committee Reviewers: (comments separated by asterisks)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): Y-4; N-0 1a. Impact: H-4; M-0; L-0; I-0; 1b. Performance Gap: H-3; M-1; L-0; I-0 Rationale: 1a Catheters have a high impact on morbidity and mortality **The range of performance was noted in the section on validity. The average prevalence of 5% seems very much below actual and may be due to reliance on short term data from CROWNWeb, which is not fully implemented and validated. **Our #1 priority!!</p> <p>1c. Evidence (based on decision logic): Y-4; N-0 IF a Health Outcome, rationale supports: Y-2; N-0; NA-2 Quantity: H-3; M-0; L-1; I-0; Quality: H-3; M-1; L-0; I-0; Consistency: H-3; M-1; L-0; I-0 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. These type studies tend not to be RCTs. No grading of the studies.</p> |
| <p>2. Scientific Acceptability of Measure Properties (based on decision logic): Y-3; N-1 2a. Reliability: H-3; M-0; L-1; I-0 2b. Validity: H-3; M-0; L-1; I-0 Rationale: Testing for month-to-month consistency in a single clinic seems a weak measurement of reliability. Using outside inspectors to measure the results in a random manner would have added reliability as would use of multiple data sources. Validity testing is not explained satisfactorily. SMR is affected by multiple factors, not only catheters. More precise associations could have been drawn from relationship with blood stream infections, adequacy, hospitalization rate. Face validity was not carried out systematically.</p> <p>2c. Disparities: H-2; M-1; L-0; I-1 Rationale: No disparities identified **No disparities were noted. This is surprising.</p> |
| <p>3. Usability: H-3; M-0; L-0; I-0 <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i> Rationale: The capture of data from CROWNWeb is not convincingly meaningful. This measure, if accurately assessed, is very useful for for both public reporting and QI.</p> |
| <p>4. Feasibility: H-4; M-0; 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> Rationale: The measure is clearly specified and should be feasible to carry out. The care processes of the local facility could lead to error in data entry.</p> |
| <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-3; N-1; A-0 Comments: In my opinion, the application did not meet Scientific Acceptability due to low scores on reliability and validity testing. This is a very important measure to have in the public domain, and this CMS Facility level measure is well specified. Should the developer be able to provide additional explanation and/or information about reliability testing and validity, I would be happy to change my overall vote at the full meeting of the SC. I suspect at least part of the problem is the developer's reliance on CROWNWeb as the data source to use for the current reliability testing--this may not yet be quite ready and the data referred to was from over one year ago.</p> |
| <p>9/9 Workgroup Call Summary The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report - Yes</p> <p>1a. Impact - Preliminary ratings indicated agreement that high impact was met.</p> <p>1b. Performance Gap – Preliminary ratings indicated agreement that there is a performance gap. 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 form Fistula first of 8% chronic catheters. The committee agreed that there is a significant performance gap.</p> <p>1c. The evidence was not further discussed – although not presented according to new guidance, sufficient evidence does exist.</p> |

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| 0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access |
| 2. Scientific Acceptability of Measure Properties - Yes 2a. Reliability – One committee member expressed some reservations about whether correlating scores across points of time with different patients was an appropriate test of reliability. The developer submitted additional testing information for the reliability (precision) of the measure score: intraclass correlation was only 0.08, but that inter-unit reliability was 0.84 -indicating the measure distinguishes among facilities. The committee was satisfied with the developer’s measure of reliability and the committee was in agreement that the criteria of reliability was met. 2b. Validity – Preliminary ratings indicated a concern by one committee member, which was resolved after reviewing the association of performance on chronic catheter use with performance on the mortality measure. 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. |
| 3. Usability - Preliminary ratings indicated agreement that usability was met. |
| 4. Feasibility - Preliminary ratings indicated agreement that feasibility was met. |
| 5. Suitable for endorsement- Yes Preliminary ratings indicated one disagreement regarding suitability for endorsement. However, that was resolved with the review and clarifications noted above. |
| If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up: |
| 10/13 Steering Committee Conference Call The workgroup was in agreement that the measure met criteria and was suitable for endorsement. 1.Importance to Measure and Report 2. Scientific Acceptability of Measure Properties 3. Usability 4. Feasibility |

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| 0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF) |
| <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>The following preliminary evaluation ratings and comments are from the Committee Reviewers: (<i>comments separated by asterisks</i>)</p> |
| <p>1. Importance to Measure and Report (<i>based on decision logic</i>): Y-4; N-0</p> <p>1a. Impact: H-4; M-0; L-0; I-0; 1b. Performance Gap: H-3; M-1; L-0; I-0</p> <p>Rationale: 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>): Y-4; N-0 IF a Health Outcome, rationale supports: Y-1; N-0; NA-3</p> <p>Quantity: H-3; M-0; L-1; I-0; Quality: H-3; M-1; L-0; I-0; Consistency: H-3; M-1; L-0; I-0</p> <p>Rationale: 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>): Y-4; N-0</p> <p>2a. Reliability: H-3; M-1; L-0; I-0 2b. Validity: H-3; M-1; L-0; I-0</p> <p>Rationale: Data gathered through CrownWEB **Full details of reliability testing not provided. 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. Validity testing here simply relates the % of AVFs to reduced SMR at individual facility. There are multiple contributors to SMR so difficult to know the attribution that should be given to increased rate of AVF--but admittedly there is some relationship. Face validity is lacking.</p> <p>2c. Disparities: H-0; M-2; L-1; I-1 Rationale: The reported lack of disparities is surprising.</p> |
| <p>3. Usability: H-4; M-0; 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: The exact definition of an "autologous AVF" was not specified. This generally should not lead to confusion. Also, the number of HD treatments per month using 2 needles in the AVF were not specified.</p> |
| <p>4. Feasibility: H-3; M-1; 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: 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>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-4; N-0; A-0</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 NQF 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>9/9 Workgroup Call Summary (In attendance: Frederick Kaskel, Andrew Narva, Constance Anderson, Jeffrey Berns, Jerry Jackson, Kristine Schonder (co-chair), Peter Crooks (co-chair), Harvey Wells)</p> <p>The following summarizes the workgroup's discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report - Yes</p> |

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| 0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF) |
| <p>1a. Impact- Preliminary ratings indicated agreement that the criteria of high impact was met.</p> <p>1b. Performance Gap- Preliminary ratings indicated agreement that the criteria of performance gap was met.</p> <p>1c. The evidence was not further discussed – although not presented according to new guidance, sufficient evidence does exist.</p> |
| <p>2. Scientific Acceptability of Measure Properties - Yes</p> <p>One committee member noted that a single needle device has been developed and should be added to definition of functional AVF. The recommendation was made to the measure developer who agreed to confer with CMS before making the change. NQF staff will follow up with measure developer and inform the Committee of any changes to the measure. 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. The Steering Committee’s discussion at the in-person meeting was in the context of patients with working grafts not being sent for evaluation by surgeon every year. However, the current clinical recommendations are to optimize fistula creation so a change in the measure was not recommended.</p> <p>2a. Reliability - Preliminary ratings indicated agreement that reliability was met.</p> <p>2b. Validity - Preliminary ratings indicated agreement that validity was met.</p> |
| <p>3. Usability- Yes - Preliminary ratings indicated agreement that usability was met.</p> |
| <p>4. Feasibility - Yes - Preliminary ratings indicated agreement that feasibility was met.</p> |
| <p>5. Suitable for endorsement - Yes 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, which will be referred to CMS.</p> |
| <p>If applicable, Conditions/Questions for Developer:</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>Steering Committee Follow-up:</p> |
| <p>10/13 Steering Committee Conference Call</p> <p>The workgroup was in agreement that the measure met criteria and was suitable for endorsement.</p> <p>1.Importance to Measure and Report</p> <p>2. Scientific Acceptability of Measure Properties</p> <p>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 CRWNWeb. 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. 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.</p> <p>3. Usability</p> <p>4. Feasibility</p> |

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| 0324 Patient Education Awareness—Facility Level |
| <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>Steering Committee Vote/Discussion 8/16-17</p> <p>1. Importance to Measure and Report (<i>based on decision logic</i>): Yes</p> <p>1a. Impact: H-11; M-9; L-1; I-0; 1b. Performance Gap: H-4; M-10; L-1; I-6</p> <p>Rationale: 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 testing on ALL modalities. Does the performance gap indicate lack of documentation vs. what education the patient reports received. In response to a question, it was 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 (<i>based on decision logic</i>): Yes IF a Health Outcome, rationale supports: NA Quantity: H-; M-2; L-6; I-13; Quality: H-1; M-3; L-4; I-13; Consistency: H-; M-1; L-4; I-16</p> <p>Rationale: 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>Exception to evidence: Y-18; N-3</p> |
| <p>Steering Committee Vote/Discussion 8/16-17</p> <p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): 2a. Reliability: H-0; M-11; L-8; I-2 2b. Validity: H-; M-; L-; I-</p> <p>Rationale: Although the developer submitted that the data will be obtained through CROWNWeb, it was noted that CROWNWeb currently does not include patient education. The developer stated that has had a 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). 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>2c. Disparities: H-; M-; L-; I- Rationale:</p> |
| <p>9/9 Workgroup Call Summary</p> <p>The following summarizes the workgroup’s discussion and subsequent action (if any) for this measure:</p> <p>1.Importance to Measure and Report</p> <p>The Steering Committee had already voted on Importance to Measure and Report at the in-person meeting and agreed to consider the measure further on the basis of an exception to the evidence criterion for expert opinion.</p> <p>2. Scientific Acceptability</p> <p>2a. Reliability – The Committee had already voted on reliability and it narrowly passed. Although the specifications indicate that CROWNWeb is the data source, currently there are no fields for patient education. NQF staff indicated that the measure is essentially a medical record measure as it was tested. That does not negatively impact reliability or validity, but could be a consideration under</p> |

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| 0324 Patient Education Awareness—Facility Level |
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| <p>Feasibility.</p> <p>2b. Validity 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? It may not be the best indicator of quality, but does it meet minimum criteria? 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>3. Usability –Preliminary ratings were spread across all the rating categories. 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 – Preliminary ratings and comments indicated differences of opinion on feasibility. 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.</p> <p>5. Suitable for endorsement –The workgroup decided to re-vote on the measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks)</p> |
| <p>1. Importance to Measure and Report (based on decision logic): Yes 1a. Impact: H-2; M-4; L-1; I-0; 1b. Performance Gap: H-2; M-3; L-1; I-1 Rationale: 1c. Evidence (based on decision logic): No Quantity: H-0; M-1; L-6; I-0; Quality: H-0; M-1; L-6; I-0; Consistency: H-0; M-1; L-4; I-2 Rationale: 0324 Despite lack of evidence that this leads to good outcomes, i would vote to continue consideration as this is widely believed to be a problem and is also mandated by Medicare for dialysis payment. 0325 For physician level the evidence is no better, and this is not a Medicare requirement for payment. Yes it is the nephrologists responsibility to participate in modality education but the onus is more on the facility. **0324 and 0320 - The evidence cited appears to be a combination of facility and physician level data but a large performance gap is reported (mean 16%, range 0-100%). I do believe, however, the issue is significant enough to warrant at least one performance measure. **Body of evidence is low with little consistency in the education data</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): No 2a. Reliability: H-0; M-2; L-3; I-3 2b. Validity: H-0; M-1; L-4; I-2 Rationale: 0324, 0320: since these measures have been endorsed for 3 years or more, I would have expected some additional testing to demonstrate that adherence to the measure in ESRD pts is definitely connected to improvement in quality of outcomes. This could have shown an increased prevalence of fistulas (or home dialysis, or transplants) in the group provided with education compared to a different group without such benefit. Rather, the application relies on demonstration of healthier choices made by pre-dialysis patients given such modality education. **0324 and 0320 – specifications indicate data from CrownWeb, but it is not clear whether the data will in fact be included in CrownWeb. The developer stated in person that they were "told that the data would be available." it is presumed so, however, as patient education is part of Conditions for Coverage.</p> <p>3. Usability: H-2; M-3; L-2; I-0 Rationale:</p> <p>4. Feasibility: H-2; M-2; L-2; I-1 Rationale: While I think a measure on Patient Awareness and Education is important, I'm not convinced the data is collected and reported is reliable to be used as a performance measure. The information given to the patient and/or their families needs to be more uniform and their needs to be consistency in evaluating the patients understanding of the information received. **0324 and 0325 - feasible high if data elements incorporated into Crown Web, else only moderate. **0324 and 0320 - High usability and feasibility because it will be included in Conditions for Coverage. As "checkbox" measures, they will be easy and feasible to use.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-3; N-4 Rationale: 0324/0320 Education and the evaluation of the patient's understanding needs to be uniform and consistent. **0324/0320 I'm also concerned that there is some confusion with these two measures on who is responsible - is it the facility or is it the physician or both. If both what's the responsibility of the physician and what is the responsibility of the facility.</p> |
| <p>If applicable, Conditions/Questions for Developer:</p> |

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| 0324 Patient Education Awareness—Facility Level |
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| <p>Developer Response: Steering Committee Follow-up:</p> <p>10/13 Steering Committee Conference Call The Steering Committee discussed 0324 and 0320 together. They have the same specifications except the level of analysis (0324-facility; 0320-clinic/in). Testing and results were different. Several clarifications were made during the discussion.</p> <p>1. Importance to Measure and Report The Steering Committee emphasized the importance of the topic area, but did not think the measure met NQF criteria for endorsement. 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. Although required by regulation, that does not prohibit endorsement of a performance measure.</p> <p>2. Scientific Acceptability of Measure Properties The submission indicates the data will come from CROWNWeb, but not currently included so the measures would be based on medical records as tested; that does not present a problem for endorsement if the reliability and validity criteria are met. One committee member questioned why no more evidence of validity for a previously endorsed measure. NQF staff noted that 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. Some steering committee members thought that the measure is essentially a checkbox of whether information was provided. Although the measure would require documentation in the record, it would be preferable to measure understanding or the patient's perception of whether received information. A committee member reported that caregiver and patient perceptions of what was taught and what education was received differ. Another committee member stated that neither of those types of measures is available and may be an impossible bar. Some committee members thought this measure was better than nothing. Other committee members disagreed because even though the topic was important, a measure still needs to meet criteria and that endorsing the measure could impede development of a better measure. A committee member questioned whether NQF has endorsed similar measure and Karen Pace said she would check. She also reminded the group that the dialysis CHAPS measure will be reviewed in 2012 and would check what is included regarding patient education. Some thought that not endorsing the measure might indicate it was not important; others thought that was not the case and could be explained and that endorsing a measure that did not meet criteria would be more problematic.</p> <p>3. Usability 4. Feasibility</p> <p>Responses to Questions <u>NQF Endorsed Measures</u> NQF has endorsed patient education measures and also removed endorsement of some patient education measures. There is no criterion that prohibits measures of whether providers gave teaching or counseling; however, the Consensus Standards Approval Committee has expressed a preference for measuring patient education and counseling from the patient's perspective. Examples of currently endorsed measures: 0307 LBP Patient Education 0519 Diabetic Foot care and patient education implemented 0394 : Hepatitis C: Counseling Regarding Use of Contraception Prior to Antiviral Treatment Examples of Measures where endorsement was not continued: 0157, 0158, 0159 Smoking cessation counseling for MI, HF, Pneumonia The primary reason these were not re-endorsed was because performance was very high so no performance gap (1b) and there were questions as to whether the measure as constructed was measuring effective counseling.</p> <p><u>In-Center Dialysis CAHPS</u> The In-Center Dialysis CAHPS measures do include a composite titled Providing Information to Patients (see below and 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> |

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| 0320 Patient Education Awareness—Physician Level |
| <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>9/9 Workgroup Call Summary</p> <p>The following summarizes the workgroup’s discussion and subsequent action (if any) for this measure: The workgroup thought all their comments related to 0324 apply to this measure because it’s essentially the same except for being applied to the individual clinician (please see 0324). The only additional discussion was a question of the need for a physician-level measure because Medicare has place 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>5. Suitable for endorsement –The workgroup decided to re-vote on the measure.</p> |
| <p>The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: <i>(comments separated by asterisks)</i></p> |
| <p>1. Importance to Measure and Report (based on decision logic): Yes 1a. Impact: H-2; M-4; L-1; I-0 1b. Performance Gap: H-1; M-4; L-0; I-2 Rationale: 1c. Evidence (based on decision logic): No Quantity: H-0; M-2; L-5; I-0; Quality: H-0; M-1; L-6; I-0 Consistency: H-0; M-1; L-4; I-2 Rationale: 0324 and 0320 - The evidence cited appears to be a combination of facility and physician level data but a large performance gap is reported (mean 16%, range 0-100%). I do believe, however, the issue is significant enough to warrant at least one performance measure.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): No 2a. Reliability: H-0; M-2; L-3; I-2 2b. Validity: H-0; M-1; L-4; I-2 Rationale: 0324, 0320: since these measures have been endorsed for 3 years or more, I would have expected some additional testing to demonstrate that adherence to the measure in ESRD pts is definitely connected to improvement in quality of outcomes. This could have shown an increased prevalence of fistulas (or home dialysis, or transplants) in the group provided with education compared to a different group without such benefit. Rather, the application relies on demonstration of healthier choices made by pre-dialysis patients given such modality education. **0324 and 0320 – specifications indicate data from CrownWeb, but it is not clear whether the data will in fact be included in CrownWeb. The developer stated in person that they were "told that the data would be available." it is presumed so, however, as patient education is part of Conditions for Coverage.</p> <p>3. Usability: H-1; M-1; L-3; I-2 Rationale:</p> <p>4. Feasibility: H-2; M-0; L-2; I-3 Rationale: While I think a measure on Patient Awareness and Education is important, I'm not convinced the data is collected and reported is reliable to be used as a performance measure. The information given to the patient and/or their families needs to be more uniform and their needs to be consistency in evaluating the patients understanding of the information received. **0320: it is not clear to me, in practical terms, how education provided to an ESRD patient "by the facility" can be separated from that provided "by the physician" in that most ESRD facilities operate as care teams, with various duties spread among team members. The physician might be the one to inform the patient about transplant, types of vascular access, and differences between CAPD and HD outcomes, but the social worker might tell the patient/family about cost differences between modalities, training times, etc. I would rather see these measures combined into a new facility measure and, as mentioned by others, include a patient comprehension component. **0324 and 0325 - feasible high if data elements incorporated into Crown Web, else only moderate. **0324 and 0320 - High usability and feasibility because it will be included in Conditions for Coverage. As "checkbox" measures, they will be easy and feasible to use.</p> |

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| 0320 Patient Education Awareness—Physician Level |
| Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-0; N-7 |
| Rationale: 0324/0320 Education and the evaluation of the patient's understanding needs to be uniform and consistent. **0320--see comments on previous page **0320 - See comments above - lack of evidence linking to desired outcome, no Medicare mandate (as for facilities), limited usefulness and inappropriately fingers the nephrologist as responsible when the role is to participate on a facility multidisciplinary team **0324/0320 I'm also concerned that there is some confusion with these two measures on who is responsible - is it the facility or is it the physician or both. If both what's the responsibility of the physician and what is the responsibility of the facility. |
| If applicable, Conditions/Questions for Developer: |
| Developer Response: |
| Steering Committee Follow-up: |
| 10/13 Steering Committee Conference Call See measure 0324 |
| 1.Importance to Measure and Report |
| 2. Scientific Acceptability of Measure Properties |
| 3. Usability |
| 4. Feasibility |

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| <p>0626 Chronic Kidney Disease - Lipid Profile Monitoring</p> <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>Steering Committee</p> <p>Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-3; M-12; L-4; I-2; 1b. Performance Gap: H-0; M-8; L-5; I-7</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): No IF a Health Outcome, rationale supports: NA Quantity: H-1; M-9; L-8; I-3; Quality: H-0; M-7; L-6; I-7; Consistency: H-0; M-4; L-5; I-12</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>2. Scientific Acceptability of Measure Properties (based on decision logic): 2a. Reliability: H-; M-; L-; I- 2b. Validity: H-; M-; L-; I-</p> <p>Rationale: Concern that CKD will be missed because of reliance on ICD or CPT codes, rather than low GFR. In registry majority are entered because of GFR rather than diagnosis by physician.</p> <p>2c. Disparities: H-; M-; L-; I- Rationale:</p> |
| <p>3. Usability: H-; M-; L-; I- (Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</p> <p>Rationale:</p> |
| <p>4. Feasibility: H-; M-; L-; 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)</p> <p>Rationale:</p> |
| <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-; N-; A- (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures)</p> <p>Comments:</p> <p>If applicable, Questions for Committee:</p> <p>If applicable, Conditions/Questions for Developer:</p> <p>Developer Response:</p> <p>Steering Committee Follow-up:</p> |
| <p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)</p> <p>Comments:</p> |
| <p>Steering Committee Recommendation for Endorsement:</p> <p>Rationale:</p> |

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0626 Chronic Kidney Disease - Lipid Profile Monitoring

10/4 Workgroup Call Summary

The Steering Committee had voted that this measure did not pass the evidence criterion. The measure developer identified that it had more evidence to support this measure and was asked to revise the submission form. Specifically, items that have been revised include: 1a.3, 1a.4, 1b.2, 1b.3, 1b.4, 1c.4, 1c.15, 2b2.3, 3.1, 5a.1, 5b.1. The measure developer has updated and edited their literature to reflect an emphasis on evidenced-based medicine and to more accurately support the measure as it is presented. They have also updated information regarding test results and evidence of performance gap. The workgroup members were asked to review the revised submission and re-evaluate the measure.

The following evaluation ratings and comments are from the Workgroup and Committee members who participated on the call: (comments separated by asterisks)**

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

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

Rationale: however, impact for pediatric patients more pronounced since large performance gap **High importance demonstrated with new additional data. **1. insufficient data on pediatric population 2. uses only esrd population and not ckd **Insufficient data on incident of lipid profiling for CKD 3- 5 **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 pts is confined to children with ESRD -- there is no data for children with other CKD stages given. There is also no specific performance gap data for children and it is unclear what proportion of pts in the 96,482 in their data base who met their numerator who they use to state that there is a performance gap were children and across what spectrum of CKD they fell. **Actually seems that testing is done in most patients; if one excludes those for whom testing is not indicated, ie very elderly, etc not really all that much of a performance gap. The bigger issue is statin treatment

1c. Evidence (based on decision logic): Yes/No? (split on quality)

Quantity: H-1; M-4; L-1; I-0 Quality: H-0; M-3; L-3; I-0 Consistency: H-0; M-5; L-1; I-0

Rationale: No RCTs **Data is appropriate based on lack of RCT in this area of CKD. The developers attempt to address pediatric issues with the data provided. Evidence presented is consistent with guidelines. **1. insufficient data on pediatric population with ckd and eskd for lipids **For subgroup CKD 3-5 of general population, benefits/harms have not been determined **Data in children not clear. Adults with CKD do appear to benefit from statins

2. Scientific Acceptability of Measure Properties (based on decision logic): Yes/No? (split on validity)

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

Rationale: Developer explained rationale for including diagnosis of hyperlipidemia for inclusion in numerator (their data system only codes diagnosis of hyperlipidemia if the patient had a lipid value drawn). Reliability and validity testing are reported for facility level and not physician level, as measure is designed. However, the developer assures that they are able to report on physician level when requested. Unclear as to why they would then propose a physician-level measure vs. facility level, as they are reporting. **Developer does not stratify even though they provide evidence for disparities in care. However, they do provide an explanation for why they do not stratify the results. 1. reliability low due to use of nephrotic syndrome codes which might capture patients with minimal change in remission at time of testing yielding normal values 2. validity low due to insufficient pilot data **The codes included for electronic retrieval of the denominator population include nephrotic syndrome codes. Since 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. I also see no validity testing done. All that is provided is a description of how the records are electronic and could be validated that way but no actual data as to verification in this fashion that has been done.

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

Rationale: Currently report results to clients who then publish results, but indicate they are working on processes for public reporting and QI. **The measure designers apply this measure to boys who are at least 10 yo and girls who are at least 13 yo. 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. It is unclear to me 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: H-2; M-3; L-1; I-0

Rationale: Measure is feasible based on current reporting strategy. ** need to use data on ckd and eskd in pediatric

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

Rationale: Meets criteria for endorsement since impact of prevention of CVD for CKD is high and prevents morbidity and mortality **This is an important measure that addresses comorbidities associated with CKD. It is the only measure to address hyperlipidemia in pediatric patients. **insufficient pilot data and data from pediatric ckd and eskd populations **use of nephrotic syndrome codes might sample pediatric patients in remission with normal lipids **Insufficient evidence for subgroup of population, individuals with CKD 3 - 5, will benefit

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0626 Chronic Kidney Disease - Lipid Profile Monitoring

from and are in need of periodic measurement of lipids. **Fails to meet several criteria as discussed above because of inclusion of younger children and because of issues with denominator CPT codes for electronic retrieval **I vote no only because of uncertainty regarding the pediatric inclusion. The only reason to measure lipids is if there is a treatment which follows that impacts outcomes. This appears to be the case for adults but the evidence for this in children seems to be lacking. I am also not convinced that that there is a meaningful performance gap **Potential for harmonization with 1668

10/13 Steering Committee Conference Call

The developer had asked to submit additional information on performance gap and testing.

1.Importance to Measure and Report

The majority of the workgroup did not think performance gap was met and the group was split on its evaluation of the evidence. The revised submission did not provide a distribution of physician level scores – overall 84% across all data.

One committee member commented that there wasn't much data specifically given to show a performance gap for children.

2. Scientific Acceptability of Measure Properties

There were differences of opinion on reliability and the group was split on its evaluation of validity. Under reliability testing, a description of data checking was provided but no empirical analysis or quantification. Under validity testing, the rate across all data (84%) was repeated.

There was some concern about how they were defining some of the population for children because Nephrotic syndrome is one of their diagnoses to electronically retrieve data and certainly children of that age group with Nephrotic syndrome really aren't the same as adults with their Nephrotic syndrome in terms of chronic kidney disease.

3. Usability

4. Feasibility

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| 1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL |
| <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>Staff Notes:</p> <p>In general the same notes in 1660 apply to this measure.</p> <p>CMS withdrew the pediatric facility-level measure of Hb<10 recommended in the recent project due to the recent FDA announcements. The evidence provided for reliability and validity of this measure appear to be the same as what was presented for the adult measure #1660 so no specific testing on the pediatric measure, but is there any reason to think it would be different?</p> <p>If the specifications and testing are the same – why are two measures needed? One measure could be stratified for adult and pediatric?</p> |
| <p>Steering Committee 8/16-17</p> <p>1. Importance to Measure and Report (based on decision logic): Yes</p> <p>1a. Impact: H-8; M-10; L-0; I-0; 1b. Performance Gap: H-0; M-9; L-0; I-11</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): Yes IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-1; M-17; L-1; I-1; Quality: H-0; M-11; L-7; I-0; Consistency: H-2; M-16; L-0; I-2</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): Yes 2a. Reliability: H-1; M-13; L-4; I-2 2b. Validity: H-0; M-16; L-1; I-2</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>2c. Disparities: H-; M-12; L-1; I-7 Rationale: Race/ethnicity in eSpecs but not in specifications.</p> |
| <p>3. Usability: H-6; M-14; 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:</p> |

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| 1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL |
| 4. Feasibility: H-12; 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> Rationale: |
| Preliminary Assessment of Criteria Met/Suitable for Endorsement: Y-17; N-2; A-0 (All criteria met, but final recommendation pending further information and/or evaluation of related and competing measures) Comments: Please provide some data in the literature that indicates performance gap. eSpecs not considered because incorrect - would need crosswalk to specifications before further consideration. If applicable, Questions for Committee: **Please note that the following question is about a standardized performance measure, NOT about the value of achieving an optimal Hgb value. What is the justification for passing this pediatric measure on evidence and not the adult measure for Hgb<10? Although there is no scientific data, the argument by the experts is that hgb<10 is significant in the pediatric patients. Measure passed based on expert opinions. Additionally, there is no evidence of harm for ESA use in children and the Committee agreed that the benefits outweigh potential harms to patients. 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. |
| Pediatric Anemia Performance Gap Data: 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. |
| Steering Committee Follow-up: |
| 5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Comments: |
| 10/4 Workgroup Call Summary The following summarizes the workgroup's discussion and subsequent action (if any) for this measure: The reason for review of this measure was to have a brief discussion with this workgroup to review the rationale for passing this measure but not the comparable adult measure. The workgroup and committee members on the call agreed that the issues for pediatric patients with hemoglobin less than ten are considerable, and in the absence of harm data with ESA use that specifically included pediatric patients, they agreed that the benefits outweighed potential harm to pediatric patients. The key points are that 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. One committee member suggested there is a need to accumulate more data using such a measure. |
| If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up: |
| 10/13 Steering Committee Conference Call |

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1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL

1. Importance to Measure and Report

The workgroup discussed the rationale for approving this measure and not the adult measure. It thought that the evidence for the harm with hemoglobin levels less than 10 in children is clear and that there is no evidence that children have been adversely affected in the studies that have prompted the FDA continuation of their concerns about ESA use. The workgroup did not suggest reconsidering either measure.

2. Scientific Acceptability of Measure Properties

3. Usability

4. Feasibility

Steering Committee Recommendation for Endorsement: Y-17; N-2; A-0

Rationale:

Follow-up on Measures Previously Evaluated by the Full Steering Committee

NQF received a letter from the developers requesting further consideration of three measures that were evaluated by the full Steering Committee at its in-person meeting and not approved as meeting the criteria to be suitable for endorsement. Although a formal comment period will occur after the Committee finishes its recommendations, if there is additional information that can inform the committee's evaluation of the measures, then that should be considered.

1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL (AMA-PCPI)

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.

1633 Blood Pressure Management (AMA-PCPI)

Karen Pace confirmed that in the current cardiovascular project, a measure that applies to all patients with hypertension (including CKD, but excluding ESRD) was recommended with the condition that it be modified when the JNC8 recommendations are published. That measure was previously endorsed rather than a new measure submitted for initial endorsement. Some committee members thought that no new information was presented in the letter; others wanted to have more discussion among the Steering Committee. The developer responded that JNC8 is not looking at new evidence and thinks that their measure is supported by current evidence. Some committee members indicated that the JNC8 guideline recommendations could be quite different than the current CKD guidelines.

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

The Steering Committee did not have time to discuss this measure.

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NEXT STEPS

A voting tool will be sent to the Steering Committee after the call. The Steering Committee will be asked to:

- vote on the measures that were reviewed by the workgroups; and
- indicate whether any of the three measures asked to be reconsidered should be re-evaluated by the Steering Committee. (As requested by committee members, NQF staff will compile the Steering Committee's prior evaluation, the developer's statements, and links to the detailed measure submission.)

For the final call on October 28, the workgroups will be asked to re-evaluate the revised measure submissions for the following measures, any additional information on measures previously reviewed, and if the Steering Committee votes to reopen evaluation of any of the three measures requested for reconsideration. On the final call the Steering Committee will have the opportunity to discuss followed by a final vote on those measures.

Revised Specifications – Need to Complete Full Evaluation

- **0251** Vascular Access—Functional AVF or Evaluation by Vascular Surgeon for Placement (Kidney Care Quality Alliance)
- **0262** Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access (Kidney Care Quality Alliance)
- **0321** Peritoneal Dialysis Adequacy: Solute (AMA-PCPI)

Additional Testing Data

- **0570** Chronic Kidney Disease (CKD): Monitoring Phosphorus (IMS Health) Steering Committee will review the resubmitted measures and any final issues.

Measure Harmonization

- Dialysis adequacy (0249 and 0323)
- Others depending on outcome of voting

Additional information submitted in response to questions at the in-person meeting.

- **1666** Patients on Erythropoiesis Stimulating Agent (ESA)--Hgb Level > or = 12g/dL (AMA-PCPI)
- **1668** Laboratory Testing (Lipid Profile) (AMA-PCPI)
- **0627** Chronic Kidney Disease with LDL Greater than or equal to 130 – Use of Lipid Lowering Agent (Active Health Management)
- **0249** Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose (CMS)
- **0323** Hemodialysis Adequacy: Solute (AMA-PCPI)
- **0259** Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula (Society of Vascular Surgeons)
- **0369** Dialysis Facility Risk-adjusted Standardized Mortality Ratio (32) Level (CMS)