NATIONAL QUALITY FORUM

END STAGE RENAL DISEASE (ESRD) PROJECT
STEERING COMMITTEE MEETING

January 11-12, 2011

Committee Members Present: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Constance Anderson, BSN, MBA; Sue Barnes, RN, BSN, CIC; Jeffrey Berns, MD; Barbara Fivush, MD; Jerry Jackson, MD; Frederick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Alan Kliger, MD; Lisa Latts, MD, MSPH, MBA; Kathe LeBeau; Joseph V. Nally, Jr., MD; Andrew Narva, MD (ex officio); Jessie Pavlinac, MS, RD, CSR, LD; Robert Provenzano, MD; JosephVassalotti, MD; Ruben Velez, MD; Harvey Wells

NQF Staff Present: Helen Burstin, MD, MPH, Senior Vice President of Performance Measures; Karen Pace, PhD, RN, Senior Program Director; Lauren Richie, MA, Project Manager; Tenee Davenport, Research Analyst.

Others Present: Tom Dudley, Centers for Medicare & Medicaid Services (by teleconference); Lisa McGonigal, Kidney Care Partners; Jose Menoyo, Genzyme Corporation; Joe Messana, Arbor Research Collaborative for Health; Robyn Nishimi, MD, Kidney Care Partners; Sylvia Ramirez, Arbor Research Collaborative for Health; Dale Singer, Renal Physicians Association (by teleconference on Day 1 and in person on Day 2); Bradley Warady, MD, University of Missouri, Kansas City School of Medicine (by teleconference); Robert Wolfe, Arbor Research Collaborative for Health

The full transcripts and audio recordings from the meeting can be found here.

MEETING PROCESS

Drs. Crooks and Schonder welcomed the Steering Committee and thanked them for their continued participation. The Steering Committee introduced themselves and stated any disclosures of interest. Dr. Crooks (Co-Chair) reviewed the purpose and agenda.

The purpose of the meeting was to:

- achieve the purpose and scope of the project;
- review and evaluate the 32 submitted measures according to NQF criteria to determine if they are suitable to recommend for endorsement as voluntary consensus standards;
- review related and competing measures to facilitate harmonization and select the best measure from among competing measures; and
- identify gaps in performance measures for ESRD care.

Dr. Pace and Ms. Richie provided background information on the National Quality Forum (NQF) and its Consensus Development Process (CDP) including an overview of the current ESRD project, the role of the Steering Committee, NQF's Measure Evaluation Criteria, and the measure evaluation and electronic voting processes.

Every measure was evaluated prior to the meeting by a subgroup of four to five Committee members. Those preliminary evaluations were entered online and the results were compiled and provided to the Committee. All Committee members participated in the final evaluation and recommendations for all measures.

The measures were grouped into several broad topic areas:

- Dialysis Adequacy and Nutrition
- Anemia
- Fluid Weight Management
- Mineral Metabolism
- Infection
- Hospitalization

Each measure was introduced by a Committee member who was asked to briefly describe the measure and summarize the preliminary Committee evaluations with particular attention to areas of concern or differences in the ratings. This introduction was followed by discussion by the entire Committee. After discussion, the Committee voted on the rating for each of the major criteria (*Importance to Measure and Report*, *Scientific Acceptability of Measure Properties*, *Usability*, and *Feasibility*) and a preliminary recommendation for endorsement.

Measure developers provided a brief introduction of their group of measures that were being reviewed that day. They were asked to address their rationale for the set of measures submitted for consideration, approach to measure development and testing, and any unique issues for specific measures. Measure developers also were asked to respond to the Committee's questions regarding specific measures as they were evaluated during the two-day meeting.

Comment periods occurred twice on each day for NQF members and the public audience to provide input to the Steering Committee. These comment periods also provided another opportunity for measure developers to address the Committee.

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EVALUATION OF END STAGE RENAL DISEASE (ESRD) MEASURES

The Steering Committee evaluated 32 measures and made preliminary recommendations for 12 measures:

- **1418** Frequency of adequacy measurement for pediatric hemodialysis patients
- **1421** Method of adequacy measurement for pediatric hemodialysis patients
- **1423** Minimum spKt/V for pediatric hemodialysis patients
- **1425** Measurement of nPCR for pediatric hemodialysis patients (time-limited)
- **1433** Use of iron therapy for pediatric patients (time-limited)
- **1424** Monthly hemoglobin measurement for pediatric patients
- **1430** Lower limit of hemoglobin for pediatric patients (conditional)
- **1438** Periodic assessment of post-dialysis weight by nephrologists (time-limited, conditional)
- **1454** Proportion of patients with hypercalcemia (conditional)
- **1463** Standardized hospitalization ratio for admissions (conditional)
- **1460** National Healthcare Safety Network (NHSN) bloodstream infection measure (preliminary pending comparison)
- **1457** Access-related bacteremia (rate) [stratified by access] (preliminary pending comparison)

All recommendations were preliminary, pending identification and review of any related or competing measures. After review of related measures for harmonization issues, the Steering Committee may make its recommendations conditional on changes needed for measure harmonization. The Committee also will select the best measure from among competing measures.

Overarching Issues

During the Steering Committee's discussion of the measures, several overarching issues emerged and were discussed. These issues factored into the Committee's ratings and recommendations for multiple measures and are not repeated in detail with each individual measure.

Importance to Measure and Report

This criterion requires that the focus of performance measures: be related to a high impact area of care; have a demonstrated performance gap; and be evidence-based or a health outcome. Many practices are important for patient care but do not rise to the level of meeting these criteria for a national standard on quality performance.

Evidence

Criterion 1c under Importance to Measure and Report requires that measures be outcomes, or if a process measure, it must be supported by evidence that it leads to a desired outcome. The measures of assessment frequency or method are only indirectly supported by evidence because the evidence base is generally for a specific intervention or intermediate outcome. Additionally, measures about the frequency of assessment are generally based on expert opinion rather than evidence. Consistent with the NQF criteria, the Steering Committee agreed that generally measures more proximal to the desired outcomes with direct evidence were preferable when they are available and supported by strong evidence. However, it was noted that the ESRD pediatric population was quite small and research and evidence are more limited. Because this is a new area for performance measurement, the Steering Committee thought a less stringent application of the criteria was appropriate.

Some intermediate outcome measures with specific threshold values were supported by evidence primarily from observational studies. Although the Steering Committee agreed that the proposed assessment parameters should be used in patient care management, it noted the limitations of the evidence on which to base a performance measure. Observational studies can provide information on important associations that should be investigated further, but cannot attribute causality. For example, observational studies that showed an association between dialysis dose and mortality led to the HEMO randomized controlled trial that compared higher to lower dialysis dose (Kt/V) when delivered three times per week; however, the trial showed no difference in mortality between the two treatment groups. Caution was urged in making conclusions based on observational studies. For example, based on observational studies, it was thought that taking hemoglobin to the normal range was the right approach, but it actually resulted in increased strokes and death. Therefore, for topics without strong evidence for specific threshold values, the Committee recommended performance measures of assessment frequency or methods rather than the intermediate outcome of specific values.

The limitation of evidence was especially problematic for the proposed fluid-volume process measures. The Steering Committee agreed with the goal of those measures, but the evidence was not sufficient to base a national standard for quality performance on it. The observational studies have confounding factors (e.g., dose and length of session). Although the processes are based on rational hypotheses and are appropriate for guiding clinical care at this time, they should not be performance measures. Perhaps measures of other indices of dialysis adequacy would be beneficial (e.g., post-dialysis weight and blood pressure; problems during dialysis such as hypotension, cramping, vomiting; nutritional status; patient function and well-being).

Performance Measures versus Guidelines or Individual Patient Management

The Committee discussed the distinction between a quality performance measure and a clinical practice guideline or individual patient management. Quality performance measures as endorsed by NQF are based on aggregated data for all relevant patients under the care of the facility or other entity whose performance is being measured and requires standardization. Performance measures should focus on relevant health outcomes or structures, processes, or intermediate outcomes that are based on strong clinical evidence of their effect on desired health outcomes. Guidelines and recommendations can include nuances and alternative treatment options to help guide the care of individual patients such as monitoring trends over time, identifying individual factors that may indicate variation in treatment, etc., which often cannot be captured in a standard performance measure.

Target Population

Most of the measures were specified for either adult or pediatric ESRD patients. Separate measures are only needed if the measure focus (e.g., lab value, intervention) is different in the various subpopulations. Some measures directly or indirectly excluded home dialysis patients. The rationale provided was lack of data for home dialysis patients; however, the clinical evidence does not vary based on the location of dialysis. A Committee member expressed concern about the ability of the facility or nephrologist to control the care of patients on home dialysis and thus should not be accountable. Others on the Committee identified that if the patient is under the care of a facility or nephrologist they should be accountable just as for other types of care and services (e.g., primary care physicians and LDL levels, home health agencies and improvement in function measures, etc.).

Patients should be included in measures based on the clinical evidence for the measure focus. Not including all relevant patients may imply a different quality standard.

The Committee identified possible modifications to the target population/denominator for some measures and these issues will be addressed further when related measures are compared. On a related note, the suggestion was made that the denominator statement should include the target age group rather than just relying on the age field on the submission form.

Data Availability/Feasibility

All of the Centers for Medicare & Medicaid Services (CMS) measures are based on data that dialysis facilities will be required to submit to the CMS CROWNweb (consolidated renal operations in a web-enabled network) data system. Large dialysis organizations tend to have electronic systems that can capture and transfer their data. Small dialysis organizations rely more on manual abstraction and data entry. The Centers for Disease Control and Prevention (CDC) infection measures require completion of a form and the CMS infection measures require much of the same information to be submitted to CROWNweb. Both sets of measures require that facilities be able to identify patients with infection and results of blood cultures. The Steering Committee recommended that the CDC and CMS data requirements be the same so that facilities could submit data once and be included in both systems.

Related and Competing Measures

Most of the new submissions had related or competing measures, either new or endorsed. The Steering Committee was directed to evaluate each measure individually on its own merits first and then those measures that met the criteria would be compared for harmonization or to select the best measure(s). Therefore, ***most of the recommendations for endorsement are provisional pending the results of those comparisons***.

Some issues that will need to be addressed include:

- Are separate measures for adult and pediatric patients warranted or can one inclusive measure be stratified as needed?
- Are the exclusions for home hemodialysis patients supported by evidence that a different standard of care applies, or should they be included?
- What is the best measure of blood stream infection?

Measures and Evaluations

Following are brief descriptions of the 32 measures reviewed, along with the Steering Committee's votes and rationale. Questions to and answers from the measure developers are also included, as well as follow-up questions to the Committee.

Dialysis Adequacy
1418 Frequency of adequacy measurement for pediatric hemodialysis patients (Recommended) **7**
1421 Method of adequacy measurement for pediatric hemodialysis patients (Recommended) **7**
1423 Minimum spKt/V for pediatric hemodialysis patients (Recommended) **8**

Nutrition
1425 Measurement of nPCR for pediatric hemodialysis patients (Recommended – Time-Limited) **9**

Anemia
1426 Assessment of iron stores **10**
1431 Measurement of iron stores for pediatric patients **10**
1428 Use of iron therapy when indicated **11**
1433 Use of iron therapy for pediatric patients (Recommended – Time-Limited) **12**
1429 Avoidance of iron therapy in iron overload **13**
1424 Monthly hemoglobin measurement for pediatric patients (Recommended) **13**
1430 Lower limit of hemoglobin for pediatric patients (Recommended – Conditional) **14**

Fluid Management
1432 Dietary sodium reduction advice **15**
1434 Sodium profiling practice for hemodialysis **16**
1435 Restriction of dialysate sodium **16**
1437 Utilization of dialysis duration of four hours or longer for patients new to dialysis **16**
1439 Utilization of high ultrafiltration rate for fluid removal **17**
1438 Periodic assessment of post-dialysis weight by nephrologists (Recommended – Time-Limited, Conditional) **17**

Mineral Metabolism
1454 Proportion of patients with hypercalcemia (Recommended – Conditional) **18**
1427 Adult dialysis patients - serum phosphorus greater than 6 mg/dl **19**
1461 Proportion of patients with hypophosphatemia **20**

Hospitalization
1463 Standardized hospitalization ratio for admissions (Recommended – Conditional) **20**
1464 Standardized hospitalization ratio for days **21**

Infection
1477 National Healthcare Safety Network (NHSN) Intravenous (IV) antibiotic start measure **21**
1460 National Healthcare Safety Network (NHSN) bloodstream infection measure (Recommended – Preliminary, pending comparison) **22**
1478 National Healthcare Safety Network (NHSN) vascular access-related bloodstream infection measure **23**

1456 Bacteremia (rate) 24
1457 Access-related bacteremia (rate) (Recommended – Preliminary, pending comparison)..... 25
1455 Access-related bacteremia—using medicare claims (rate)..... 26
1449 Unavailable blood culture results (percentage) 27
1453 Clinically confirmed infection (rate) 28
1469 Clinically confirmed access-related infection (rate)..... 28
1450 Unavailable clinical confirmation (percentage)..... 29

LEGEND: Y- 'Yes'; N-'No'; C- Completely; P- Partially; M-Minimally; N-Not at all

1418 Frequency of adequacy measurement for pediatric hemodialysis patients
Description: Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month Numerator Statement: Number of patients in the denominator with monthly adequacy measurements (spKt/V) or its components in the calendar month. Denominator Statement: Number of pediatric patients (less than18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis) who are in the facility and on hemodialysis for the entire study period. Exclusions: Patients on home dialysis, patients not in the facility for the entire calendar month. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-17; N-3 Rationale: Vulnerable population, so error on side of endorsing measures.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-18; N-2 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Addresses a vulnerable population. Although frequency of measuring dose is not proximal to the outcome and the evidence is about adequate dose, measuring dose is necessary and there is a demonstrated performance gap—20% do not have dose reported. On a related measure, the Committee discussed the lack of basis for excluding home hemodialysis patients, who also need to receive adequate dialysis.
2. Scientific Acceptability of Measure Properties: C-5; P-11; M-4; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: Specifications are precise and reliability of Kt/V data element demonstrated. Only face validity addressed and systematic assessment not reported.
3. Usability: C-12; P-7; M-1; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: In order to improve adequacy of dose, need to measure dose.
4. Feasibility: C-15; P-5; M-; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Easily collected by CMS data collection system.

1421 Method of adequacy measurement for pediatric hemodialysis patients
Description: Percentage of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period Numerator Statement: Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified. Denominator Statement: Number of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis.

1421 Method of adequacy measurement for pediatric hemodialysis patients
Exclusions: Patients on home dialysis, patients not in the facility for the entire calendar month. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic Health/Medical Record CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-11; N-9 Rationale: The appropriate measurement of adequacy in pediatric HD patients will likely improve outcomes in children. The reason for the split vote was due to exclusion of home hemodialysis patients, which Committee members thought was a critical flaw in the measure.
If applicable, Conditions/Questions for Developer: Can you clarify that this measurement is for a single dialysis session (e.g., explicitly state in title, numerator, denominator)?
1. Importance to Measure and Report: Y-19; N-1 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although the method for assessing dose is not proximal to the outcome and the evidence is about adequate dose, it is critical to appropriately measure the adequacy of hemodialysis in pediatric patients. The developer provided additional information that 20% of pediatric patients do not have delivered dose measured. The exclusion of home hemodialysis patients was questioned because those patients also need adequate dosing. The developer stated it was due to lack of data, not based on the clinical evidence. The Committee discussed that standard Kt/V would allow all patients regarless of frequency to be included in the measure of minimum adequacy.
2. Scientific Acceptability of Measure Properties: C-6; P-13; M-1; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: Specifications are precise. Method is associated with frequency of dialysis but this measure is just about method for a single session so either method (UKM, Daugirdas) in numerator is ok. The Committee suggested explicitly identifying in the title and specifications that the method is for a single session. Reliability of method data element demonstrated. Only face validity addressed and systematic assessment not reported.
3. Usability: C-6; P-11; M-2; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: In order to improve adequacy of dose, need to accurately measure dose.
4. Feasibility: C-7; P-11; M-2; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The data elements needed are easily collectable and reliable through the proposed CROWNweb system.

1423 Minimum spKt/V for pediatric hemodialysis patients
Description: Percentage of all pediatric (less than18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/Vgreater than or equal to1.2 Numerator Statement: Number of patients in the denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V>=1.2 Denominator Statement: Number of pediatric (less than18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly. Exclusions: Patients on home hemodialysis, patients on hemodialysisless than90 days, patients receiving dialysis less than3x/week or greater than 4x/week, patients not in the facility for the entire calendar month. Adjustment/Stratification: No risk adjustment necessary N/A Stratification of target values by age was considered, with higher targets for younger patients, however, there are insufficient data to support any stratified target measures at this time. Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-11; N-9 Rationale: The rationale for recommending for endorsement is that a minimal level for HD adequacy is important in pediatric patients.

1423 Minimum spKt/V for pediatric hemodialysis patients
The rationale for not recommending is a question of evidence for setting the minimal dose at 1.2 and perhaps should be higher in pediatric patients and the question of using spKt/V for different frequencies of dialysis.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-13; N-7 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although there is question of whether 1.2 is the correct target and whether it is appropriate for all ages up to 18, there is some evidence that <1.2 is linked to poorer outcomes in pediatric patients. Some Committee members advocated that a minimally acceptable target was needed; and others cautioned that if endorsed in a performance measure, the minimal may become the standard. At present there are opportunities for improvement in this area—with a number of pediatric patients not receiving adequate minimal HD.
2. Scientific Acceptability of Measure Properties: C-4; P-6; M-6; N-4 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The specifications are precise. It was noted that if you assess adequacy of dialysis for patients dialyzing at different frequencies (as specified in this measure), then the measure should be standard Kt/V not single pool Kt/V. One of the pediatric Committee members stated that the goal was to include as many patients as possible in the denominaotr so included frequency of 3-4 days. Another Committee member commented that's the reason for using standard Kt/V—the patient getting dialyzed 4x/wk is going to have a lower spKt/V and look worse even though actually has better urea removal. A pediatric Committee member stated that they think it's the younger patients having dialysis 4x/wk and they want them to meet the 1.2 with each treatment becasue they need it (actually represents different standard in one measure). Reliability of the spKt/V element was demonstrated. Only face validity addressed and systematic assessment not reported.
3. Usability: C-4; P-12; M-4; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The measure is meaningful and will positively affect patient care. It is useful for public reporting, and easily understood by multiple audiences.
4. Feasibility: C-7; P-10; M-3; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Reliable data entry for this measure are already in place and are commonly used to report to CMS. The feasibility of measurement without error is high..

1425 Measurement of nPCR for pediatric hemodialysis patients
Description: Percentage of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements Numerator Statement: Number of patients in the denominator with monthly nPCR measurements. Denominator Statement: Number of all pediatric (less than18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements. Exclusions: Patients on home dialysis, patients not in the facility for the entire one-month study period. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Time-Limited Y-12; N-8 Rationale: The rationale for recommending this measure is that this measure of nutrition, nPCR, can be easily calculated and give important information about the nutrition of pediatric HD patients. Its use can result in improved longterm outcomes in pediatric patients. The rationale against recommending this measures is that the evidence is not robust enough to qualify this as a performance measure.
If applicable, Conditions/Questions for Developer: As stated, the denominator has the same information as the numerator. It is assumed that the last part of the denominator statement should be removed. Can you please clarify if this is the case?
1. Importance to Measure and Report: Y-14; N-6 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Good nutrition and protein intake are critical in the pediatric ESRD patient. The nPCR is a better marker of nutritional status than serum albumin. Measuring lab values is not proximal to desired outcomes. Additionally, there is little to no evidence about specific

1425 Measurement of nPCR for pediatric hemodialysis patients
target values or interventions to change them, so it raises the question of whether appropriate for a performance measure. However, the Committee thought that measuring nPCR has the potential for high impact in dialysis prescription when used in combination with Kt/V.
2. Scientific Acceptability of Measure Properties: C-3; P-13; M-4; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure is untested but the specifications are precise.
3. Usability: C-6; P-7; M-6; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Although measuring nutrition alone will not improve nutritional outcomes, it is the first step in addressing an important issue for pediatric patients.
4. Feasibility: C-7; P-11; M-2; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The data are routinely generated and the calculation of the measure is similar to the measure of frequency of measuring Kt/V. Facilities already report the data electronically.

1426 Assessment of iron stores
Description: Percentage of all adult (greater than or equal to18 years old) dialysis patients for whom serum ferritin and transferrin saturation percentage (TSAT) are measured simultaneously at least once during the three-month study period. Numerator Statement: Number of patients in the denominator for whom serum ferritin and TSAT are measured simultaneously at least once during the study period. Simultaneous measurements are those reported with the same collection date. Denominator Statement: All adult (>=18 years old) hemodialysis or peritoneal dialysis patients in the facility for the entire three-month study period. Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A N/A Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare and Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-5; N-13 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: This measure was intended to replace endorsed measure #0252 (removing measurement of CHr). Measuring a lab value is not proximal to the desired outcome. A measure of hemoglobin value is a better indicator of management of anemia and quality of care. There is no evidence that serum ferritin and TSAT need to be measured simultaneously.

1431 Measurement of iron stores for pediatric patients
Description: Percentage of all pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hbless than11.0 g/dL in at least one month of the study period for whom serum ferritin concentration and percent transferrin saturation (TSAT) are measured at least once in a three-month period Numerator Statement: Number of dialysis patients in the denominator for whom serum ferritin concentration and percent transferrin saturation (TSAT) are measured at least once in a three-month study period for all hemodialysis and peritoneal dialysis patients. Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients prescribed an erythropoiesis-stimulating agent (ESA) at any time during the study period or who have a hemoglobin less than11.0 g/dL in at least one month of the study period. The hemoglobin value reported for the end of each study period (end-of-month hemoglobin) is used for this calculation. Exclusions: Patients who are not in the facility for the entire three-month study period. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process

1431 Measurement of iron stores for pediatric patients
Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-9; N-11 Rationale: Rationale for recommending the measure is primarily that pediatric measures are needed. Rationale against recommending the measure is the same as for the adult measure—obtaining lab values is not proximal to desired outcome and measure of Hb values is a better measure of anemia management.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-11; N-9 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Measuring lab values is not proximal to desired outcomes and the evidence presented was about anemia and treatment of anemia rather than measuring iron values. There is no evidence that serum ferritin and TSAT need to be measured simultaneously. However, some Committee members thought that this measure focus could be acceptable in a new area of performance measurement for pediatric patients.
2. Scientific Acceptability of Measure Properties: C-3; P-12; M-5; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: Measure specifications are precise. Reliability of data elements for ferritin and TSAT demonstrated. Face validity referenced but no description of systematic assessment.
3. Usability: C-5; P-10; M-5; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The information obtained could be understandable and useful to impact use of iron therapy in pediatric anemic patients.
4. Feasibility: C-7; P-10; M-2; N-1 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: One member expressed concern about the complexity and number of data elements required; however, others noted that all the data elements are collected now via the CMS data system and can be easily used in the measure.

1428 Use of iron therapy when indicated
Description: Percentage of all adult (greater than or equal to18 years old) dialysis patients with a serum ferritin less than 100 ng/mL and a transferrin saturation percentage (TSAT) less than 50% on at least one simultaneous measurement who received IV iron in the following three months. Numerator Statement: Number of patients in the denominator who received IV iron within three months following the first occurrence of serum ferritin less than 100 ng/mL and TSAT less than 50% during the study period. Denominator Statement: All adult (greater than or equal to18 years) hemodialysis (HD) and peritoneal dialysis (PD) patients in the facility for the entire three-month reporting period who had serum ferritin less than100 ng/mL and TSAT less than50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date. Exclusions: 1. Patients with mean hemoglobin (Hgb) greater than 12g/dl who did not receive an erythropoietin stimulating agent (ESA) during the three-month study period. The last recorded Hgb value of each month of the study period will be used in calculating the mean. 2. Patients with documented history of anaphylaxis to IV iron products. Adjustment/Stratification: No risk adjustment necessary N/A N/A Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-5; N-15 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Iron therapy is indicated for iron deficiency anemia and might limit doses of ESAs. However, the evidence presented was

1428 Use of iron therapy when indicated

about patients treated with ESAs to higher target hemoglobin levels, not about effectiveness of iron therapy or the relationship of iron therapy to ESA use. Iron therapy guidelines are opinion-based. The facility scores at 75th percentile were 100% indicating that ESRD patients are receiving iron therapy. The developer provided additional information that 3,700 patients were not receiving iron therapy out of 10,000 who met the denominator specifications. The values specified in the measure are not well-grounded in the evidence. The specification of TSAT <50% eliminates virtually no additional patients besides those with ferritin <100 ng/ml. Iron deficiency anemia is defined as ferritin <30 rather than <100. The exclusion of Hb>=12 may be too high because 12 is the upper limit and perhaps should be 10. The values used in the measure could lead to inappropriate IV iron, which exposes patients to harm. If Hb is 11.5 and slightly deficient in other values, iron might not be clearly indicated. Even if Hb <10, with a ferritin of 90 does not mean the patient is iron deficient. The measure includes PD patients but does not allow oral iron therapy. Missing is consideration of evaluation of the cause of iron deficiency; trends over time in TSAT, ferritin, and hemoglobin; as well as intensity of iron administration in response to the test results obtained. Anemia management is important and an intermediate outcome of hemoglobin levels is a better measure.

2. Scientific Acceptability of Measure Properties: C-; P-; M-; N-

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale:

3. Usability: C-; P-; M-; N-

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale:

4. Feasibility: C-; P-; M-; N-

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)

Rationale:

1433 Use of iron therapy for pediatric patients

Description: Percentage of all pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin less than11.0 g/dL and in whom simultaneous values of serum ferritin concentration was less than100 ng/ml and TSATless than20% who received IV iron or were prescribed oral iron within the following three months

Numerator Statement: Number of patients in the denominator who received IV iron or were prescribed oral iron within three months following the first occurrence of serum ferritin less than100 ng/mL and transferrin saturation (TSAT) less than20% during the study period.

Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period with hemoglobin less than11 g/dL and in whom simultaneous values of serum ferritin were less than100 ng/mL and TSATless than20% during the three-month study period.

Exclusions: Patients who are not in the facility for the entire three-month study period.

Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.

Level of Analysis: Facility/Agency

Type of Measure: Process

Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network)

Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Time-limited because key data elements regarding iron therapy not tested.

Y-14; N-6

Rationale: The measure has a better description of iron deficiency than the adult measure (1428) with TSAT <20%. Iron therapy is indicated for iron deficiency anemia and might limit doses of ESAs.

If applicable, Conditions/Questions for Developer: Why are simultaneous values for ferritin and TSAT required?

1. Importance to Measure and Report: Y-13; N-7

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: The measure has a better description of iron deficiency than the adult measure (1428) with TSAT <20% but data on sensitivity and specificity of ferritin and TSAT levels in children were not identified. Iron therapy is indicated for iron deficiency anemia and might limit doses of ESAs. Iron therapy guidelines are opinion-based. No specific data on a performance gap was provided. No evidence was provided to support Hb level <11; however, the pediatric specialists indicated that 11 was accepted as the threshold for anemia in pediatric patients. New data suggests that cytokines interfere with erythropoiesis, which may make these values more important. Ferritin levels may be age-dependent, which might suggest it is less useful as a marker. However the pediatric experts

1433 Use of iron therapy for pediatric patients
advocated this measure to emphasize proactive management. There is no evidence that ferritin and TSAT need simultaneous measurement.
2. Scientific Acceptability of Measure Properties: C-4; P-11; M-4; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: Measure specifications are precise. Reliability of data elements for lab values presented, but nothing about iron therapy, the central topic of the measure; therefore, this will be considered untested. Mentioned face validity, but did not provide any description of systematic assessment. Could meet measure by prescribing oral iron even if not taken or responsive or inappropriate for HD patients, which call into question the validity as a quality indicator. What happens if ferritin and TSAT values are not simultaneous—excluded from denominator?
3. Usability: C-3; P-14; M-3; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: If valid, could provide information about appropriate management of anemia.
4. Feasibility: C-7; P-11; M-2; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Data generated from routine care and reported electronically. Is there an unintended consequence of overuse of iron therapy?

1429 Avoidance of iron therapy in iron overload
Description: Percentage of all adult (greater than or equal to18 years old) dialysis patients with a serum ferritin greater than or equal to1200 ng/mL or a TSAT greater than or equal to50% on at least one simultaneous measurement during the three-month study period who did not receive IV iron in the following three months. Numerator Statement: Number of patients in the denominator who did not receive IV iron within three months following the first occurrence of serum ferritin greater than or equal to1200 ng/mL or TSAT >=50% during the study period. Denominator Statement: All adult (>=18 years) hemodialysis (HD) and peritoneal dialysis (PD) patients in the facility for the entire three-month reporting period who had serum ferritin >=1200 ng/mL or TSAT >=50% on at least one simultaneous measurement reported during the three-month study period. Simultaneous measurements are those reported with the same collection date. Exclusions: None Adjustment/Stratification: No risk adjustment necessary N/A N/A Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-9; N-11 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The rationale for considering this criterion met is the consequence of potential harm of IV iron overload. The rationale for considering this criterion as not met was related to inadequate evidence. Evidence of levels associated with harm were not identified. The definition of iron overload in dialysis patients (this measure is not limited to HD) is not evidence-based. Most dialysis patients have adequate bone marrow iron stores with ferritin >100-300 ng/ml so on this basis alone continued iron administration may be excessive in some patients. A better indicator of excess iron administration would be an increasing ferritin level. TSAT >= 50% is very rare so is largely irrelevant in this measure (40% may be a better upper limit); hence the measure is really focused on ferritin >1200 ng/ml. The developer provided additional information that in a sample from CROWNweb, out of 40,000 patients who met the denominator criteria, only 10,000 did not receive IV iron in the following 3 months. However, this raised the question of timing of the lab values in relation to prior IV iron administration.

1424 Monthly hemoglobin measurement for pediatric patients
Description: Percentage of all pediatric (less than18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin

1424 Monthly hemoglobin measurement for pediatric patients
Numerator Statement: Number of pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation. Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients. Exclusions: Patients who are not in the facility for the entire calendar month. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-20; N-0 Rationale: Although measuring hemoglobin value is not proximal to the desired outcome and the evidence provided was about the relationship between hemoglobin levels and outcomes, the current poor performance data warrants the use of this measure.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-19; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although measuring hemoglobin value is not proximal to the desired outcome and the evidence provided was about the relationship between hemoglobin levels and outcomes, the current poor performance data warrants the use of this measure. In a 2008 study, hemoglobin was reported in less than three of the six study months in 29% of pediatric ESRD patients, and was not reported in any of the six study months for 11% of patients.
2. Scientific Acceptability of Measure Properties: C-15; P-5; M-; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure is precisely specified. Reliability demonstrated for "Hb >=9", but measure is based on Hb value and collection date. Face validity mentioned, but no description of systematic assessment.
3. Usability: C-18; P-2; M-; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: The information provided by this measure is meaningful, understandable, and useful to providers and patients.
4. Feasibility: C-18; P-1; M-; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Data for the measure are in the process of being collected via the ESRD CPM and units are familiar with the procedure.

1430 Lower limit of hemoglobin for pediatric patients
Description: Percentage of pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients, with ESRD >=3 months, who have a mean hemoglobin less than10 g/dL for a three-month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation. Numerator Statement: Number of pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients, with End Stage Renal Disease (ESRD) greater than or equal to3 months, who have a mean hemoglobin less than10.0 g/dL for a three-month reporting period, irrespective of erythropoiesis stimulating agent (ESA) use. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation. Denominator Statement: All pediatric (less than18 years old) hemodialysis and peritoneal dialysis patients with ESRD greater than or equal to3 months Exclusions: Patients on dialysis less than3 months at the start of the reporting period, patients who are not in the facility for the entire one-month study period. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Conditional Y-18; N-2 Rationale: Anemia is related to morbidity and mortality and how patients feel and function. The provided data indicated 14%-19% of

1430 Lower limit of hemoglobin for pediatric patients
pediatric patients had hemoglobin levels <10 g/dl in 2007.
If applicable, Conditions/Questions for Developer: Conditions: 1) exclude patients with sickle cell anemia, 2) numerator—number of patients with Hb<10 for each of three months (Y-13; N-7)
1. Importance to Measure and Report: Y-19; N-0 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Anemia is related to morbidity and mortality and how patients feel and function. The provided data indicated 14%-19% of pediatric patients had hemoglobin levels <10 g/dl in 2007; more recent data are not provided. Although there is little to no evidence in the pediatric population for a specific value, the Committee agreed that there is no evidence it should be different from the adult measure.
2. Scientific Acceptability of Measure Properties: C-; P-; M-; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: Did not vote on rating because of recommended changes. Patients with sickle cell anemia are harmed with Hb >9 and should be excluded. Patients could have increasing trends and still be included in the numerator as specified. Some Committee members advocated for a change from average <10 to <10 in each of the three months (Y-13; N-7) in order to identify persistent anemia. When hemoglobin is <10 need to take action and a performance measure should identify when action is inadequate. Other Committee members advocated for the average over three months as specified because the measure aggregates data from all patients and is an indicator of how well anemia is managed overall; it is not intended for clinical management of individual patients. The three-month average takes into account biologic variability. The propsed change focuses on outliers versus overall management. Additionally, a measure using the avearge would be harmonized with the adult measure. When asked, the developer indicated their Technical Expert Panel did not discuss persistently low hemoglobin.
3. Usability: C-; P-; M-; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Did not vote on rating because of recommended changes
4. Feasibility: C-; P-; M-; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Did not vote on rating because of recommended changes. The developer indicated the change was possible with the data available.

1432 Dietary sodium reduction advice
Description: The proportion of patients who have received formal advice on dietary sodium restriction by the renal dietician within the past 90 days Numerator Statement: Number of patients in the denominator who have received formal advice on dietary sodium restriction by the renal dietician within the past 90 days. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance dialysis. Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-5; N-15 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although dietary salt restriction is appropriate and evidence-based, the focus of this measure is on dietary advice. There is insufficient evidence linking dietary advice to sodium intake, to impact on volume, and to its consequences. No basis for the 90-day period was provided. It is measured from the provider perspective and is susceptible to becoming a documentation/checkbox measure, or being fulfilled by just giving patients an information sheet. There is a critical need for measures of patient self-management addressed from the patient perspective, e.g., whether the patient reports receiving counseling or what is learned; however, this measure does that.

1432 Dietary sodium reduction advice
Some Committee members noted that patients may not be aware of link between sodium intake and volume and even with the flaws in the measure, it will raise awareness of need to address dietary sodium.

1434 Sodium profiling practice for hemodialysis
Description: Proportion of patients who were not prescribed sodium profiling in the reporting month Numerator Statement: Number of patients in denominator who were not prescribed sodium profiling in the reporting month. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance HD. Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-4: N-16 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: No data on prevalence of sodium profiling or performance gap was presented. Evidence regarding the use and consequences of the practice was weak. No discussion of when sodium profiling might be appropriate (e.g., those particularly prone to intradialytic hypotension). The measure is based on a reasonable hypothesis that sodium profiling causes excess sodium transfer, leading to increased volume and its consequences, but it has not been adequately studied to warrant a performance measure.

1435 Restriction of dialysate sodium
Description: Proportion of patients who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L for all sessions in the reporting month Numerator Statement: Number of patients in denominator who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L in the reporting month. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD). Exclusions: None. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-2; N-18 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: No data are available concerning the frequency of dialysate sodium >138, and no sub-group analysis of dialysate sodium use has been done. The measure is based on a reasonable hypothesis, but not strong evidence. No evidence supporting the specific threshold of 138 was provided.

1437 Utilization of dialysis duration of four hours or longer for patients new to dialysis
Description: The proportion of patients new to dialysis whose prescribed dialysis session length is at least 240 minutes Numerator Statement: Number of patients in denominator whose prescribed dialysis session length is at least 240 minutes. Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis. Exclusions: Patients not receiving dialysis treatment three times per week. Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb

1437 Utilization of dialysis duration of four hours or longer for patients new to dialysis

Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

If applicable, Conditions/Questions for Developer:

1. Importance to Measure and Report: Y-6; N-14
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: While it is clear that several outcomes are better when "more" dialysis is compared with "less" treatment, and also that there is wide variation in dialysis prescription across dialysis facilities; the specific link to longer dialysis sessions when prescribed for 3x/wk has less support. More frequent hemodialysis treatments (>3x/wk) improves solute clearance (e.g., urea measured by Kt/Vurea) and removal of volume; however, there is little convincing evidence that a cut-off of four hours of treatment when delivered 3x/wk provides better outcomes. There is little evidence regarding subsets of patients (e.g., small patients, very large patients) who may have different metabolic requirements for dialysis. There is some data showing improved outcomes from nocturnal dialysis (in-center 3x/wk for 6-8 hr); however, it is not definitive for a specific cut-off. The DOPPS study showed correlation between longer dialysis and survival, e.g., in Australia the average is 4.5 hr. The DOPPS is an observational study and there were other correlations, not just length of session. The HEMO randomized controlled trial failed to show improved outcomes with higher delivered dose, but it did not study differences in time or frequency (delivered in 2.5-4.5 hr, 3x/wk). KDOQI will have a clinical practice guideline out by the end of this year and KDIGO probably 18 months after that.
Some Committee members thought that even with the limitations on evidence, the four-hour timeframe was sufficiently established to warrant a performance measure and that four hours should be considered a minimum standard. However, a question was raised as to why this would only be applicable to new patients rather than all.

1439 Utilization of high ultrafiltration rate for fluid removal

Description: Proportion of patients who did not receive an ultrafiltration rate greater than or equal to 15 ml/kg/hr in the reporting month
Numerator Statement: Number of patients in the denominator who did not receive an ultrafiltration (UF) rate greater than or equal to 15 ml/kg/hr for the month's reported dialysis session.
Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD).
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

If applicable, Conditions/Questions for Developer:

1. Importance to Measure and Report: Y-4; N-14
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: No data on prevalence or performance gap was presented. While there are some published data showing that high ultrafiltration rates correlate with reduced survival, there is no clear evidence that a "cut-off" of 15 ml/kg/hr is an appropriate standard of care. In the observational studies, high ultrafiltration rate is confounded with short sessions. Potential harm from this approach, i.e., inadequate fluid removal in some high-risk patients, etc. has not been assessed. The quoted guideline focuses on intermediate outcomes of euvolemia and normotensive, not the specific ultrafiltration rate.

1438 Periodic assessment of post-dialysis weight by nephrologists

Description: The proportion of patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month.
Numerator Statement: Number of patients in denominator who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month.
Denominator Statement: Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD).
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure.
Level of Analysis: Facility/Agency
Type of Measure: Process

1438 Periodic assessment of post-dialysis weight by nephrologists

Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Time-limited; Conditional
Y-20; N-0
Rationale: The Committee thought that some measure to highlight the importance of fluid and weight management was necessary and this is the best measure that can be used at this time due to the issues discussed with the other measures on this topic. Additionally, there are no potential unintended harms from implementing this measure.

If applicable, Conditions/Questions for Developer: Condition: include pediatric
Question: Should "new" be removed from description and simply refer to post-dialysis weight?

1. Importance to Measure and Report: Y-18; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: The Committee thought that some measure to highlight the importance of fluid and weight management was necessary. Although no information was provided on a performance gap, there was consensus among the Committee members that there was a gap in performance on routinely assessing weight. Assessing weight is not proximal to desired outcomes; however, it is the best measure that can be used at this time due to the issues discussed with the other measures on this topic. Additionally, there are no potential unintended harms from implementing this measure. The Committee agreed that there is no reason it should not apply to pediatric patients. When asked if it should also apply to home hemodialysis patients, the comment was made that monthly might not be appropriate.

2. Scientific Acceptability of Measure Properties: C-9; P-8; M-2; N-
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: The specifications for a "new" post-dialysis weight prescription may imply it must be changed; whereas, patients should have a post-dialysis weight assessment every month even if the prescription does not change. It was unclear what information will be entered in CROWNweb to identify whether the numerator is met (e.g., just a yes/no or date and prescription). The measure is untested so reliabiity and validity are not known.

3. Usability: C-9; P-9; M-2; N-
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: The measure may provide initial information regarding fluid weight management.

4. Feasibility: C-7; P-8; M-5; N-
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: Data would be collected and acted upon as part of process of care and will be included in the CMS data system.

1454 Proportion of patients with hypercalcemia

Description: Proportion of patients with three-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL
Numerator Statement: Number of patients in the denominator with three-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL
Denominator Statement: Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one calcium measurement during the prior 90 days.
Exclusions: None
Adjustment/Stratification: No risk adjustment necessary N/A N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Conditional Y-18; N-2
Rationale: Although evidence for a specific threshold value is weak, the 10.2 value is the upper limit of normal and higher values represent toxicity of therapies prescribed for dialysis patients. Unlike the measure of high phosphorous, hypercalcemia represents a marker of toxicity from drug therapies and the response is to decrease those therapies rather than lead to more drug therapies and potential additional toxicities.

If applicable, Conditions/Questions for Developer: Condition: 1) numerator # of pts w/ total uncorrected Ca >10.2 for each of 3

1454 Proportion of patients with hypercalcemia

months (Y-13; N-7)

1. Importance to Measure and Report: Y-16; N-4

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Although evidence for a specific threshold value is weak, the 10.2 value is the upper limit of normal and higher values represent toxicity of therapies prescribed for dialysis patients. In 2009-2010, 13,690 patients (4.5%) had values >10.2 and in 95% (n = 3,318) of the 3,493 facilities, 13% of patients were hypercalcemic. Hypercalcemia is likely the result of therapies—calcium, Vitamin D, calcium-based binders. Uncorrected calcium is appropriate because of the variability associated with methods to calculate corrected calcium.

Unlike the measure of high phosphorous, hypercalcemia represents a marker of toxicity from drug therapies and the response is to decrease those therapies rather than lead to more drug therapies and potential additional toxicities.

2. Scientific Acceptability of Measure Properties: C-; P-; M-; N-

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

Rationale: Did not vote on rating because of recommended changes.

It was suggested to limit the denominator to patients receiving therapies that lead to hypercalcemia. The developer pointed out that it is difficult to identify when over-the-counter drugs are used and the Committee agreed it would be important to include all patients.

Some Committee members advocated for a change to >10.2 in each of the three months (Y-13; N-7) This is consistent with using trends for patient management. Patient could have decreasing trend and still be included in the numerator. When asked, the developer said that would be possible with the data.

Other Committee members advocated for the average over three months as specified because the measure aggregates data from all patients and is an indicator of overall management; it is not intended for clinical management of individual patients.

3. Usability: C-; P-; M-; N-

(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)

Rationale: Did not vote on rating because of recommended changes

4. Feasibility: C-; P-; M-; N-

(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)

Rationale: Did not vote on rating because of recommended changes.

The developer indicated the proposed change was possible with the data available.

1427 Adult dialysis patients—serum phosphorus greater than 6 mg/dl

Description: Proportion of patients with three-month rolling average of serum phosphorus greater than 6 mg/dL

Numerator Statement: Number of patients with three-month rolling average of serum phosphorus greater than 6 mg/dL

Denominator Statement: Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one phosphorus measurement during the prior 90 days

Exclusions: None

Adjustment/Stratification: No risk adjustment necessary race, ethnicity

Level of Analysis: Facility/Agency

Type of Measure: Outcome

Data Source: Electronic administrative data/claims; Electronic clinical data; Lab data When available, the electronic data can be entered into CROWNWeb either through manual web-based entry or batch transmission for larger organizations.

Measure Steward: Genzyme Corporation | 500 Kendall Street | Cambridge | Massachusetts | 02142

Steering Committee Recommendation for Endorsement: No

Rationale: Did not pass Importance to Measure and Report

If applicable, Conditions/Questions for Developer:

1. Importance to Measure and Report: Y-7; N-13

(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)

Rationale: Establishing a specific threshold value has not been definitively identified in the evidence. Although observational studies have shown increased risk of mortality with high levels of phosphorus, different reference ranges and comparison values have been analyzed. Some Committee members commented that no interventional studies have been conducted, so the impact on morbidity and mortality of lowering phosphorus is not known. Use of calcium-based versus non calcium based binders is a very controversial area.

1427 Adult dialysis patients—serum phosphorus greater than 6 mg/dl

Other Committee members noted that increasing dialysis time brings values closer to normal. KDOQI guidelines are opinion-based and KDIGO experts did not recommend performance measure. Some Committee members noted caution in making conclusions based on observational studies. We used to think that getting hemoglobin to normal was a reasonable goal, but efforts to do so caused more mortality.
The developer commented that at the facility level, those with levels >6 vs. 3.5-5 have poorer outcomes.
The rationale for considering this criterion not met is that it is an intermediate outcome without sufficient evidence for setting a threshold value or that interventions to lower phosphorous have an effect on morbidity or mortality. The rationale for considering this criterion met is that it is an intermediate outcome linked to higher mortality and therefore should be measured and reported.

1461 Proportion of patients with hypophosphatemia

Description: Proportion of patients with three-month rolling average of serum phosphorus less than 2.5 mg/dL
Numerator Statement: Number of patients in the denominator with three-month rolling average of serum phosphorus less than 2.5 mg/dL
Denominator Statement: Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one phosphorus measurement during the prior 90 days.
Exclusions: None.
Adjustment/Stratification: No risk adjustment necessary N/A N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Electronic clinical data CROWNWeb
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: No
Rationale: Did not pass Importance to Measure and Report

If applicable, Conditions/Questions for Developer:

1. Importance to Measure and Report: Y-2; N-17
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Hypophasphatemia is a marker for malnutrition. Establishing a specific threshold value has not been definitively identified in the evidence; however, 2.5 is the lower limit of the normal range. 2009 data indicated that 0.6% of the ESRD patients had phosphorus <2.5 and 29% of facilities had at least one patient that met the criteria. Hypophasphatemia can be affected by intensity of dialysis. These patients are often very sick and malnourished with high mortality and it is not clear that feeding them will help.

1463 Standardized hospitalization ratio for admissions

Description: Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.
Numerator Statement: Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.
Denominator Statement: Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.
Exclusions: None.
Adjustment/Stratification: Risk adjustment devised specifically for this measure/condition N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Public health data/vital statistics; Electronic Health/Medical Record
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Conditional Y-18; N-2
Rationale: The measure addresses an NPP goal and while risk adjustment may be complex, the reporting of hospitalization is important and useful.

If applicable, Conditions/Questions for Developer: Conditions: 1) Need to remove race/ethnicity from risk model or provide justification supported by data and analysis. 2) Change time period to one year rather than three or provide data and analysis that stable estimates require more data.
Question: What is data source? Submission says public health/vital statistics and EHR. Shouldn't it be claims data?

1. Importance to Measure and Report: Y-20; N-0
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Hospitalizations are a proxy outcome for deteriorating health status. The measure relates to an NPP goal and is important to

1463 Standardized hospitalization ratio for admissions
measure in the ESRD population. A few Committee members suggested that hospitalization was not under the control of ESRD facilities or clinicians. Other Committee members identified that when patients are managed well the number of hospitalizations is decreased. No one suggests that all hospitalizations can be avoided.
2. Scientific Acceptability of Measure Properties: C-7; P-12; M-1; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The Committee questioned the need for a three-year time period and the developer indicated that one year was acceptable. NQF criteria indicate that race and ethnicity (often associated with disparities in care) should not be used as factors in risk models.
3. Usability: C-8; P-9; M-3; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Usability was not demonstrated. Some Committee members questioned actionability by providers of ESRD care. Other Committee members noted that dialysis care and things such as management of anemia, vascular access, and fluid can directly influence hospitalizations. Therefore, hospitalization rates can be used to identify when care processes should be examined for improvement.
4. Feasibility: C-12; P-6; M-2; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The measure is based on claims data and requires no additional data collection.

1464 Standardized hospitalization ratio for days
Description: Risk-adjusted standardized hospitalization ratio for days for dialysis facility patients. Numerator Statement: Number of days hospitalized among eligible patients at the facility during the reporting period. Denominator Statement: Number of days hospitalized that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility. Exclusions: None. Adjustment/Stratification: Risk adjustment devised specifically for this measure/condition N/A Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic administrative data/claims; Public health data/vital statistics Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-4; N-16 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: When asked why this measure was needed, the developer indicated it was a measure of complexity. The Committee identified that how long a patient stays in the hospital is not just an indicator of patient condition when admitted, but also hospital practices and quality. Therefore, it should not be a performance measure.

1477 National Healthcare Safety Network (NHSN) Intravenous (IV) antibiotic start measure
Description: Monthly rate of outpatient intravenous antibiotic starts (initiation of a new antibiotic not in use in previous 21 days) per 100 patient months within outpatient dialysis unit. The 21-day rule is used to exclude counting antibiotics that are given for the same infection. Numerator Statement: Total number of intravenous antibiotics started (not in use in previous 21 days) in the outpatient unit. Denominator Statement: The denominator is the number of patients receiving hemodialysis at the facility on the first two hemodialysis days of the month (i.e., patient-months). Exclusions: Patients receiving outpatient hemodialysis during the month during which surveillance is being conducted but not present in the facility during the first two calendar days of the month are not included in the denominator Adjustment/Stratification: Analysis by subgroup Level of Analysis: Facility/Agency; Population: national Type of Measure: Other—This measure is both process and outcome

1477 National Healthcare Safety Network (NHSN) Intravenous (IV) antibiotic start measure
Data Source: Paper medical record/flow-sheet; Pharmacy data; Electronic clinical data; Electronic Health/Medical Record National Healthcare Safety Network (NHSN) Dialysis Event form (numerator)—collected with each event NHSN ouptaient dialysis denominator form (denominator—collected monthly Measure Steward: Centers for Disease Control and Prevention | 1600 Clifton Road NE, Mailstop A-31 | Atlanta | Georgia | 30333
Steering Committee Recommendation for Endorsement: Y-2; N-18 Rationale: Although an important topic for measurement, the validity, usabiity, and feasibility were concerns.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-12; N-8 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare-associated infection is an NPP goal and outcome measures do not require evidence - they should be outcomes that are relevant to the target population. Some Committee members questioned using antibiotic starts as a proxy for infection given some of the issues with inappropriate antibiotic use.
2. Scientific Acceptability of Measure Properties: C-2; P-12; M-6; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: It was not clear if antibiotic starts for patients admitted after the first two days (who often have catheters and higher risk of infection) are included. In response to questions about the specifications, the developer clarified that the denominator statement of patients on first two days of the month is just to minimize the burden of data collection, but all antibiotic starts in the month are counted in the numerator. No specific reliabiity testing was reported, but data element valdity was conducted. Data element validity testing was conducted on a small sample. A Committee member questioned the adequacy of the results (e.g., of 85 recent IV antibiotic starts that were identified by the facilities in the study, 59 (69.4%) had an appropriate surveillance form completed for the event).
3. Usability: C-1; P-12; M-7; N- *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: There was some confusion that the measure was intended to identify inappropriate antibiotic starts rather than as proxy for infection.
4. Feasibility: C-0; P-9; M-11; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Requires data collection and reporting. No clear plan for electronic data capture. The CDC NHSN reporting system has been in place for a considerable time. The data collection form is not commonly used in dialysis facilities.

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure
Description: Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months Numerator Statement: The number of new positive blood culture events based on blood cultures drawn as an outpatient or within one calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient. Denominator Statement: Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first two working days of the month. Exclusions: Patients receiving inpatient hemodialysis are excluded Adjustment/Stratification: Other Simple stratification Level of Analysis: Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels Type of Measure: Outcome Data Source: Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis 57.109 Dialysis Event Measure Steward: Centers for Disease Control and Prevention | Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31 | Atlanta | Georgia | 30333
Steering Committee Recommendation for Endorsement: Preliminary pending comparison Y-13; N-7 Rationale: Needs to be compared to competing measures to determine the best measure for endorsement.
If applicable, Conditions/Questions for Developer: Clarify "during a month that the outpatient unit is performing surveillance"—does that mean the data are not collected continuously? Will denominator specifications for first two days of the month miss incident dialysis patients who have the highest risk of catheters for

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure
access, of infections and readmission to the hospital.
1. Importance to Measure and Report: Y-17; N-2 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare associated infections is an NPP goal and outcome measures do not require evidence. There is variation in performance.
2. Scientific Acceptability of Measure Properties: C-4; P-16; M-; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: It was not clear if the specifications will miss incident dialysis patients who have the highest risk of catheters for access, of infections, and readmission to the hospital. In response to questions about the specifications, the developer clarified that the denominator statement of patients on first two days of the month is just to minimize the burden of data collection, but all blood stream infections in the month are counted in the numerator. "During a month that the outpatient unit is performing surveillance" implies that the data are not collected continuously—is that appropriate? Data element validity testing was conducted on a small sample and results were satisfactory (88%, 89%, 78%). Type of vascular access is a primary risk factor for blood stream infection and the measure is stratified by type of access. It was questioned whether including all infections even if not related to dialysis (e.g., diabetic foot ulcer) was a valid quality indicator. However, all infections are important.
3. Usability: C-6; P-10; M-3; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Measure of bloodstream infection would be usable for both public reporting and quality improvement.
4. Feasibility: C-1; P-9; M-9; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The CDC NHSN reporting system has been in place for a considerable time although the data collection form may not be commonly used in dialysis facilities. A feasibility issue was raised about getting blood culture results for patients who had been admitted to the hospital. However, dialysis facilities need to obtain information on hospitalized patients when they return to dialysis, and bloodstream infection would be important information. Dialysis facilities would not need to obtain other than their usualinformation on hospitalized patients. Colorado has mandated use of these NHSN measures, and other states are expected to follow. Twenty-two states have mandated NHSN for HAIs. It would be best if NHSN and CROWNweb could transfer data so that facilities could use either system for reporting. Some concern was expressed about the incentive to not identify those positive blood cultures on hospital admission.

1478 National Healthcare Safety Network (NHSN) vascular access-related bloodstream infection measure
Description: Number of hemodialysis outpatients with positive blood cultures and in whom the suspected source was reported as either the vascular access or unknown, per 100 hemodialysis patient-months Numerator Statement: The number of bloodstream infections that are suspected to be related to the vascular access—i.e., not including positive blood cultures that likely reflect contamination nor that represent secondary bloodstream infections with a nonvascular primary site of origin. Denominator Statement: Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first two working days of the month. Exclusions: Patients receiving inpatient hemodialysis are excluded Adjustment/Stratification: Other Simple stratification Level of Analysis: Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels Type of Measure: Outcome Data Source: Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis 57.109 Dialysis Event Measure Steward: Centers for Disease Control and Prevention | 1600 Clifton Rd., MS A-31 | Atlanta | Georgia | 30333
Steering Committee Recommendation for Endorsement: Y-4; N-16 Rationale: While the topic is important, the subjectivity of attributing infection to vascular access and the impact on validity makes it questionable as a performance measure.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-12; N-8 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare associated infections is an NPP goal and outcome measures do not require evidence. There is variation

1478 National Healthcare Safety Network (NHSN) vascular access-related bloodstream infection measure

in performance. The rationale for considering that this criterion was not met is the lack of evidence for identifying the cause of a bloodstream infection, especially given that 1460 stratifies bloodstream infection by access type and that all bloodstream infections are important. However, other Committee members noted that vascular access infections were most appropriate to measure for ESRD care.

2. Scientific Acceptability of Measure Properties: C-2; P-11; M-7; N-
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)
Rationale: A primary issue was lack of specificity for determining if the infection was related to vascular access. Each facility can decide how and who makes that determination. CDC just provides a list of common skin contaminants for them to consider. A question was raised as to whether this will miss incident dialysis patients coming from the hospital who have the highest risk of catheters for access, of infections, and readmission to the hospital. Patients who are transiting at another clinic, those who are no-shows or who are hospitalized on one of those two days of the month would be excluded and infections missed. The developer clarified that the denominator statement of patients on first two days of the month is just to minimize burden of data collection but all infections in the month are counted in the numerator.Data element validity testing was conducted on a small sample and results were not strong for identifying source of infection. Of 53 positive blood cultures where suspected source was reported to the surveillance system and reviewed, 63.9% were determined to have been correctly characterized and reported. Type of vascular access is primary risk factor and the measure is stratified by type of access.

3. Usability: C-2; P-9; M-7; N-1
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)
Rationale: Usable only if it can be accurately determined that the infection is attributed to vascular access so it does not provide any advantage over the simpler measure of bloodstream infections (1460).

4. Feasibility: C-0; P-8; M-10; N-2
(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)
Rationale: The CDC reporting system has been in place for a considerable time although the data collection form may not be commonly used in dialysi facilities. The feasibility of getting blood culture results for patients who had been admitted to the hospitalwas questioned. However, dialysis facilities need to obtain information on hospitalized patients when they return to dialysis, and bloodstream infection would be an important piece of information.

1456 Bacteremia (rate)

Description: Six-month rolling average rate of bacteremia with IV antibiotic therapy, among adult chronic HD patients (Express as: rate per 1000 HD patient days)
Numerator Statement: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which blood cultures were consistent with bacteremia.
Denominator Statement: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month.
Exclusions: Patients less than 18 years old.
Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type (fistula/graft/catheter).
Level of Analysis: Facility/Agency
Type of Measure: Process
Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network)
Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244

Steering Committee Recommendation for Endorsement: Y-9; N-11
Rationale: Should this measure also be compared to competing measures to determine the best measure for endorsement?

If applicable, Conditions/Questions for Developer: Do you have any testing data on reliability and validity? Can you clarify why you indicated as a process measure if it is being used as a marker for infection? Did you intend to develop process measures about diagnosing and treating infections? Can you clarify or provide reference to regulatory requirements for ESRD facilities to provide data to CROWNweb?

1. Importance to Measure and Report: Y-16; N-4
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Reducing healthcare associated infections is an NPP goal and outcome measures do not require evidence. The developer categorized the measure as a process measure, but it appears to be an outcome measure. On the submission, it was asserted there

1456 Bacteremia (rate)
was large variation across dialysis facilities but no data were presented. The Committee agreed that reducing all bacteremias is an important goal.
2. Scientific Acceptability of Measure Properties: C-1; P-15; M-4; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This is an untested measure The numerator requires both IV antibiotic start and positive blood cultures, but the denominator is all ESRD patients, so it is a measure of bacteremia not a process measure. Although the developer states there are too few pediatric patients for a meaningful measure, is there any reason to exclude pediatric patients from a measure that would cover all ESRD patients? Type of vascular access is primary risk factor and the developer states that the measure could be stratified by type of access.
3. Usability: C-0; P-11; M-7; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: A reliable and valid measure of infection would be useful.
4. Feasibility: C-1; P-11; M-8; N-0 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Required data is mandated in CROWN web. The numerator requirement for both antibiotic starts and positive blood culture was seen as potentially more burdensome than focusing on just positive blood culture. However, the understanding is that the data are required in CROWNweb regardless of what quality measures are endorsed.

1457 Access-related bacteremia (rate)
Description: Overall access-related bacteremia: Six-month rolling average rate of access-related bacteremia with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients (Express as: rate per 1000 HD patient days) Specific access types: Six-month rolling average rate of fistula/graft/catheter-related bacteremia with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using a fistula/graft/catheter for HD access (Express as: rate per 1000 fistula/graft/catheter patient days) Numerator Statement: Overall access-related bacteremia: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was related to the HD access, and blood cultures were consistent with bacteremia. Specific access types: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was related to the fistula/graft/catheter used as HD access, and blood cultures were consistent with bacteremia. Denominator Statement: Overall access-related bacteremia: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month. Specific access types: All adult (18+) chronic maintenance HD fistula/graft/catheter days during the six-month period ending with the current reporting month. Exclusions: HD patients less than 18 yrs old. Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type as noted in the numerator and denominator statements. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare and Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Preliminary pending comparison Time-limited Y-11; N-9 Rationale: Needs to be compared to competing measures to determine the best measure for endorsement.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-18; N-2 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare associated infections is an NPP goal and outcome measures do not require evidence. The developer categorized this measure as a process measure, but it appears to be an outcome measure. Although a large variation across dialysis facilities was asserted in the submission, no data were presented. Nonetheless, the Committee agreed that reducing all bacteremias is

1457 Access-related bacteremia (rate)
an important goal and access-related are most directly related to dialysis care.
2. Scientific Acceptability of Measure Properties: C-3; P-11; M-5; N- *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This is an untested measure The numerator requires three elements: IV antibiotic start, positive blood cultures, and determination that infection is related to vascular access, but the denominator is all ESRD patients, so it is a measure of bacteremia not a process measure. It requires a determination that the infection was related to vascular access but provides no definitions or guidance. Although the developer states there are too few pediatric patients for a meaningful measure, is there any reason to exclude pediatric patients from a measure that would cover all ESRD patients? Type of vascular access is the primary risk factor for infection and the measure is stratified by type of access.
3. Usability: C-0; P-15; M-3; N-2 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: If reliable and valid, the information would be meaningful and useful.
4. Feasibility: C-0; P-15; M-4; N- *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: Required data is mandated in CROWNweb. The CMS representative siad that the conditions of coverage published in 2007 require facilities to submit 100% of data required by CMS. The developer said it was essentially the same information as needed for CDC measure.

1455 Access-related bacteremia—using medicare claims (rate)
Description: Overall access-related bacteremia: Six-month rolling average rate of access-related bacteremia among adult chronic hemodialysis (HD) patients (Express as: rate per 1000 HD patient days) Specific access types: Six-month rolling average rate of fistula/graft/catheter-related bacteremia among adult chronic hemodialysis (HD) patients using a fistula/graft/catheter for HD access (Express as: rate per 1000 days of fistula/graft/catheter use) Numerator Statement: Overall access-related bacteremia: For the months in the denominator, number of months in which a monthly hemodialysis claim reported an access-related bacteremia using HCPCS modifier V8. Specific access types: For the months in the denominator, number of months in which a monthly hemodialysis claim reported an access-related bacteremia using HCPCS modifier V8 with the particular type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month. Denominator Statement: Overall access-related bacteremia: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month. Specific access types: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month with the particular type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month. Exclusions: HD patients less than 18 yrs old. Adjustment/Stratification: No risk adjustment necessary N/A As stated in numerator and denominator statements, this measure can be stratified by type of access (fistula/graft/catheter) as indicated by HCPCS modifiers V5, V6, or V7 for vascular access in use at the end of the preceding month. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic administrative data/claims Medicare claims Measure Steward: Centers for Medicare and Medicaid | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-7; N-13 Rationale: The measure is not tested and claims data is thought to be inferior source of data compared to record abstraction.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-14; N-6 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Reducing healthcare associated infections is an NPP goal and outcome measures do not require evidence. Developer categorized as a process measure but it appears to be an outcome measure. On the submission it was asserted there was large

1455 Access-related bacteremia—using medicare claims (rate)
variation across dialysis facilities but no data were presented. The Committee agreed that reducing all bacteremias is an important goal.
2. Scientific Acceptability of Measure Properties: C-0; P-15; M-4; N-1 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This is an untested measure that will be based on claims data rather than the clinical data reported in CROWNweb. In response to a question of why an identical measure with a different data source was submitted, the CMS representative said it was because of uncertainty regarding the timing of CROWNweb. There was a question of whether claims are reliable and valid in identifying bacteremia using HCPCS modifiers. Although the developer states there are too few pediatric patients for a meaningful measure, is there any reason to exclude pediatric patients from a measure that would cover all ESRD patients? There is no definition or guidance on how to determine that a bacteremia is access-related. There may be the potential for counting a single episode of infection twice in a case where this episode bridges two calendar months and the modifier is used in each of those months. In response to a question as to why this has to be Medicare claims versus any claim, the developer stated they only had access to Medicare claims.
3. Usability: C-0; P-14; M-4; N-3 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: If reliable and valid, the information would be meaningful and useful.
4. Feasibility: C-4; P-9; M-6; N-1 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The requirement for reporting this on the claim form already exists, so this does not add another layer of reporting.

1449 Unavailable blood culture results (percentage)
Description: Six-month rolling average prevalence of "unavailable" blood culture results for adult chronic hemodialysis (HD) patients prescribed IV antibiotics (Express as: percentage) Numerator Statement: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month and for which blood culture results were indicated to be "unavailable". Denominator Statement: Number of months that adult (18+) HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month. Exclusions: HD patients less than 18 yrs old, or not prescribed an IV antibiotic. Adjustment/Stratification: No risk adjustment necessary This measure can be stratified by vascular access type (fistula/graft/catheter). Level of Analysis: Facility/Agency Type of Measure: Structure/management Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare and Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-1; N-18 Rationale: The Committee did not think the measure was necessary or appropriate for pubic reporting.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-9; N-9 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: No data on performance gap was provided. The rationale for considering this criterion met is if the measure is viewed as a process measure of performing blood cultures. The rationale for considering this criterion not met is that it is primarily a measure of missing data used in conjunction with other measures.
2. Scientific Acceptability of Measure Properties: C-1; P-6; M-9; N-3 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: This is an untested measure. Unavailable was not defined. Does unavailable include not ordered and not done? Why are pediatric patients excluded?
3. Usability: C-1; P-4; M-10; N-4 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: As a measure being used to detect "gaming of the system," this measure might have some usefulness. As a process measure, there is some usefulness. However, a measure of missing data is not particularly useful for pubic reporting or quality

1449 Unavailable blood culture results (percentage)
improvement.
4. Feasibility: C-2; P-5; M-10; N-2 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions – no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The measure is based on absence of data in the field in CROWNweb.

1453 Clinically confirmed infection (rate)
Description: Six-month rolling average rate of clinically confirmed infection with IV antibiotic therapy among adult chronic HD patients (Express as: rate per 1000 HD patient days) Numerator Statement: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was clinically confirmed. Denominator Statement: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month. Exclusions: Patients less than 18 years old. Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type (fistula/graft/catheter). Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Withdrawn Rationale: The developer withdrew the measure when 1469 was not recommended because all three clinical confirmation measures would be needed.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Withdrawn *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The developer withdrew the measure when 1469 was not recommended because all three clinical confirmation measures would be needed.

1469 Clinically confirmed access-related infection (rate)
Description: Clinically confirmed infection: Six-month rolling average rate of clinically confirmed infection with IV antibiotic therapy among adult chronic HD patients (Express as: rate per 1000 HD patient days) Specific access types: Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an arteriovenous fistula for HD access (Express as: rate per 1000 HD fistula days) Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using an arteriovenous graft for HD access (Express as: rate per 1000 HD graft days) Six-month rolling average rate for access-related infection with IV antibiotic therapy, among adult chronic hemodialysis (HD) patients using a catheter for HD access (Express as: rate per 1000 HD catheter days) Numerator Statement: Clinically confirmed infection: Number of months that hemodialysis (HD) patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which the infection was clinically confirmed and related to the dialysis access. Specific access types: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection that was clinically confirmed during the six-month period ending with the current reporting month and for which the infection was related to the fistula/graft/catheter used as HD access. Denominator Statement: Clinically confirmed infection: All adult (18+) chronic maintenance HD patient days during the six-month period ending with the current reporting month. Specific access types: All adult (18+) chronic maintenance HD fistula/graft/catheter days during the six-month period ending with the current reporting month.

1469 Clinically confirmed access-related infection (rate)
Exclusions: HD patients less than 18 yrs old (for all access types) Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type as noted in the numerator and denominator statements. Level of Analysis: Facility/Agency Type of Measure: Process Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare & Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Y-2; N-16 Rationale: The evidence and measure specifications did not address how to clinically confirm an infection or how to determine it was related to vascular access.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Y-9; N-9 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Measure listed as process, but really an outcome. It was not constructed as the process of clinically confirming an infection. The evidence did not address how to clinically confirm an infection or how to determine it was related to vascular access. However, the outcome of infection is extremely important.
2. Scientific Acceptability of Measure Properties: C-0; P-9; M-6; N-3 *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: The measure is untested and the specifications do not define clinically confirmed or vascular access-related so may not get consistent results. Could be some problem with shift to oral antibiotics.
3. Usability: C-0; P-4; M-12; N-1 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: If data are not consistent, the information will not be usable.
4. Feasibility: C-0; P-2; M-13; N-3 *(4a. Clinical data generated during care process; 4b. Electronic sources; 4c. Exclusions—no additional data source; 4d. Susceptibility to inaccuracies/ unintended consequences identified 4e. Data collection strategy can be implemented)* Rationale: The data elements are to be collected in CROWNweb.

1450 Unavailable clinical confirmation (percentage)
Description: Six-month rolling average prevalence of "unavailable" information regarding clinical confirmation of infection among adult chronic hemodialysis (HD) patients with new IV antibiotic prescription (Express as: percentage) Numerator Statement: Number of months that HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month, and for which an indication of "unavailable" was provided regarding whether the infection was clinically confirmed or related to dialysis access. Denominator Statement: Number of months that adult (18+) HD patients initiated a new IV antibiotic therapy for a newly suspected infection during the six-month period ending with the current reporting month. Exclusions: HD patients less than 18 yrs old, or not prescribed an IV antibiotic. Adjustment/Stratification: No risk adjustment necessary N/A This measure can be stratified by vascular access type (fistula/graft/catheter). Level of Analysis: Facility/Agency Type of Measure: Structure/management Data Source: Electronic clinical data CROWNWeb Measure Steward: Centers for Medicare and Medicaid Services | 7500 Security Boulevard | Baltimore | Maryland | 21244
Steering Committee Recommendation for Endorsement: Withdrawn Rationale: The developer withdrew the measure when 1469 was not recommended because all three clinical confirmation measures would be needed.
If applicable, Conditions/Questions for Developer:
1. Importance to Measure and Report: Withdrawn *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The developer withdrew the measure when 1469 was not recommended because all three clinical confirmation measures would be needed.

QUALITY PERFORMANCE MEASURES GAP

The Committee identified several priority areas for additional quality performance measures for the care of ESRD patients:

- patient education for self-management (*measured from the patient perspective*);
- patient-reported outcomes (e.g., "functional wellness");
- care coordination and transitions of care
    - from Chronic Kidney Disease to ESRD (successful preparation for ESRD, i.e., optimal ESRD starts – preemptive kidney transplant, home dialysis, or in-center hemodialysis with a functioning AV fistula);
    - from pediatric to adults; and
    - between settings (e.g., in-center to home, Skilled Nursing Facility to in-center; hospital to dialysis center)
- appropriate use of more intensive therapy (including hemodialysis frequency and duration);
- fluid/weight management (*the Committee decided the submitted measures were not adequate*);
- end-of-life/palliative care;
- disparities; and
- optimal management of other co-morbid disease states (e.g., diabetes, hypertension, cardiovascular disease)

NEXT STEPS

Conditions for recommendation and any additional questions will be sent to the measure developers for responses. The Steering Committee will review all its recommendations, measure developer responses, and harmonization and competing measures on a follow-up conference call. The Committee will revote on measures with conditional recommendations and other measures as needed (e.g., competing measures, conditions related to harmonization, etc.). The Committee also will continue to discuss gaps in quality performance measures.