NATIONAL QUALITY FORUM

CONFERENCE CALL FOR END STAGE RENAL DISEASE (ESRD) STEERING COMMITTEE

May 6, 2011

Committee Members Participating via Conference Call: Peter Crooks, MD (Co-Chair); Kristine Schonder, PharmD (Co-Chair); Constance Anderson, BSN, MBA; Jeffrey Berns, MD; Jerry Jackson, MD; Frederick Kaskel, MD, PhD; Myra Kleinpeter, MD, MPH; Kathe LeBeau; Joseph V. Nally, Jr., MD; Jessie Pavlinac, MS, RD, CSR, LD; Robert Provenzano, MD; JosephVassalotti, MD; Ruben Velez, MD; Harvey Wells

Committee Members Not Present on Call: Barbara Fivush, MD; Alan Kliger, MD; Lisa Latts, MD; Andrew Narva, MD; Roberta Wager, RN, MSN

NQF Staff Present on Call: Karen Pace, PhD, MSN, Senior Program Director; Lauren Richie, MA, Project Manager; Tenee Davenport, Project Analyst

Others Present on Call: Akhtar Ashfaq, Amgen; Claudia Dahlerus, Arbor Research Collaborative for Health; Tom Dudley, Centers for Medicare & Medicaid Services; Sarah Freelich, Genzyme; William Goodman, Amgen; Renee Henry, Centers for Medicare & Medicaid Services; Alissa Kapke, Arbor Research Collaborative for Health; Sheri Ling, Arbor Research Collaborative for Health; Jose Menoyo, Genzyme; Joe Messana, Arbor Research Collaborative for Health; Robyn Nishimi, MD, Kidney Care Partners; Tom Nusbickel; Amgen; Holly Owens, Amgen; Daniel Pollock, Centers for Disease Control and Prevention; Tayo Stone, Amgen; Robert Wolfe, Arbor Research Collaborative for Health

WELCOME AND INTRODUCTIONS

After roll call of the Steering Committee members, Drs. Crooks and Schonder welcomed the Steering Committee members and thanked them for their continued participation. Dr. Crooks (Co-Chair) then reviewed the agenda before discussions and review of the measures began.

The purpose of this follow-up call was for the ESRD Steering Committee to review and discuss the comments received during the NQF Public and Member Comment period and determine what responses and/or course of action may be needed. The measure developers/stewards were available on the call to respond to questions from the Committee as needed. An NQF Member and public comment period occurred at the end of the call; no comments were made at that time. The full transcripts and audio recordings from the conference call can be found on the project web page.

The Committee finished its review of additional topic areas to be included in the list of performance gaps for measure development for ESRD care and additional responses from the measure developers via e-mail after the call.

PUBLIC AND MEMBER COMMENTS

The ESRD Public and Member Comment period closed on 4/22. A total of 161 comments from 32 individuals or organizations were received on measures both recommended and not recommended for endorsement as well as some general comments on the Draft Report. Please see the ESRD project page for a spreadsheet of all of the comments received including final responses from the Steering Committee. In addition, some of the comments were referred to the measure developers and their responses have been included along with the Committee's responses.

The following themes were identified in the comments received and were addressed by the Steering Committee. A summary of comments and responses are provided for each measure in the evaluation summary tables that follow.

Measures Recommended

Expand target population

- **Include home hemodialysis and peritoneal dialysis patients in the measures unless evidence requires exclusion**

  1418 - Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
  1424 - Monthly Hemoglobin Measurement for Pediatric Patients
  1433 - Use of Iron Therapy for Pediatric Patients
  1438 - Periodic Assessment of Post-Dialysis Weight by Nephrologists
  1454 - Proportion of patients with hypercalcemia (also one recommendation that a lower limit of serum calcium be incorporated to create a target range of 8.4-10.2 mg/dL)

- **Include CKD stage 3 and 4 in anemia measures**

  1424 - Monthly Hemoglobin Measurement for Pediatric Patients
  1430 - Lower Limit of Hemoglobin for Pediatric Patients
  1433 - Use of Iron Therapy for Pediatric Patients

Question Whether Measures Meet NQF Criteria

1418 - Frequency of Adequacy Measurement for Pediatric Hemodialysis
1421 - Method of Adequacy Measurement for Pediatric Hemodialysis Patients
1425 - Measurement of nPCR for Pediatric Hemodialysis Patients
1424 - Monthly Hemoglobin Measurement for Pediatric Patients
1438 - Periodic Assessment of Post-Dialysis Weight by Nephrologists

Harmonize or combine with adult measures

1421 - Method of Adequacy Measurement for Pediatric Hemodialysis Patients
1423 - Minimum spKt/V for Pediatric Hemodialysis Patients

1463 – Standardized Hospitalization Ratio for Admissions -Multiple comments were submitted to recommend only inclusions of hospitalizations related to the outcomes of dialysis treatment. In addition, the Committee was asked to fully examine the methodology that goes into the calculation of expected hospitalization rate.

1460 - National Healthcare Safety Network (NHSN) Bloodstream Infection Measure
(all comments received were in support of this measure)

Measures NOT Recommended

1427 – Adult dialysis patients-serum phosphorus greater than 6 mg/dl - Multiple comments were submitted to reconsider endorsement for this measure on basis that the evidence is just as strong as for the hypercalcemia measure and that this measure may eventually be required in a future bundled payment program.

CMS submitted rationales for all the measures not recommended and asked for reconsideration of endorsement for the following measures:

- **1431- Measurement of iron stores for pediatric patients**
- **1464- Standardized hospitalization ratio for days**
- **1434- Sodium profiling practice for hemodialysis**
- **1435- Restriction of dialysate sodium**
- **1432- Dietary sodium reduction advice**

Priorities for Measure Development
Several recommendations were submitted for additional topic areas to be included in the list of priorities for performance measure development for ESRD care.

- Antimicrobial resistance
- Prevention of catheter-related infections and thrombosis
- Iron therapy management
- Lower level of serum calcium
- Serum phosphorus
- Use of standard Kt/V in measures of dialysis adequacy so that all dialysis patients can be included
- End-of-life/palliative care (advanced care-planning, symptom management, bereavement)
- Use of standard Kt/V so that hemodialysis patients on any treatment schedule can be included

The Committee had previously recommended the use of standard Kt/V so that hemodialysis patients on any treatment schedule can be included in measures of dialysis adequacy and agreed it should be added to the list of priorities. The Committee noted that end-of-life/palliative care was already on the list of priorities for measure development. The Steering Committee reviewed the other recommendations via email and responses are included in the posted table of comments.

NEXT STEPS

The Steering Committee's and measure developer responses will be included in the final evaluation summaries in the Draft Report for the NQF Member Voting period. NQF Members will have 30 days to consider the evaluations and comments and responses to the measures thus far to inform their votes.

EVALUATION SUMMARY TABLES

Evaluation Summary—Candidate Consensus Standards Recommended for Endorsement

The summary of the comments and subsequent actions can be found in the evaluation summary tables below.

1418 Frequency of adequacy measurement for pediatric hemodialysis patients
For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings
Description: Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis or home (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month. 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 or home 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.~~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, MD 21244
Steering Committee Recommendation for Endorsement: Y-17; N-3 Rationale: Although not proximal to desired outcome, there is a performance gap and children are a vulnerable population, so error on side of endorsing measures.
If applicable, Conditions/Questions for Developer: Developer Response: Steering Committee Follow-up: Related Measure: 0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—Monthly measurement of delivered dose (previously endorsed) Recommendation: In the future, preferably combine into one measure stratified for adult and pediatric (including home HD if possible). For all measures of dialysis adequacy (frequency, method, and results), the Committee recommends switching to measuring standard Kt/V so that all patients canbe combined regardless of frequency and one measure can be stratified by adult and pediatric. What would be required to move to that measurement? Would a standard Kt/V accommodate home patients who may have adequacy measured on

1418 Frequency of adequacy measurement for pediatric hemodialysis patients
a weekly basis? Is there a standard Kt/V threshold that would apply to all patients and all frequencies? Developer Follow-up: The CTEP did not discuss stdKt/V as an option for measuring dialysis adequacy. In addition, based on our literature review, evidence that evaluates the impact of dialysis adequacy is based on spKt/V. This has implications in identifying a cut-off for stdKt/V in the pediatric population. Based on these points, we propose that the current measure remain as developed by the TEP with the use of spKt/V. In addition, we suggest that the use of stdKt/V be re-evaluated with a future TEP when more evidence regarding its use in the pediatric population becomes available.
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, i.e., 20% do not have dose reported. On a related measure (#1421), 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-0 *(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 is demonstrated. Only face validity addressed; systematic assessment not reported.
3. Usability: C-12; P-7; M-1; N-0 *(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-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: Easily collected by CMS data collection system.
Public and Member Comment Comments included: • support of the measure; • question whether it meets NQF's criteria for Importance to Measure and Report; and • include home hemodialysis patients. The Steering Committee addressed the issues raised regarding Importance to Measure and Report while evaluating the measure as noted above and in Overarching Issues. The Committee upheld its recommendation for endorsement because pediatric ESRD care is a new area of performance measurement and there was less than optimal performance. This will be re-evaluated at the time of endorsement maintenance. The Committee asked the measure developer to review the specifications for inclusion of home patients or provide rationale for their exclusion. Developer Response: The measure developer agreed to include home hemodialysis patients and submitted revised specifications as indicated above and in the specifications Table in Appendix A.

1421 Method of adequacy measurement for pediatric hemodialysis patients

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

Description: Percentage of pediatric (less than18 years old) in-center ~~HD~~ hemodialysis patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.
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~~ hemodialysis patients (irrespective of frequency of dialysis) in the sample for analysis.
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, MD 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 vote was split because of the 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)?
Developer Response: "We propose revising the numerator statement to the following:
'Number of patients in the denominator for whom delivered HD dose for a single dialysis session was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified.' "
Steering Committee Follow-up: Related measure 0248: Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose (previously endorsed)
Recommendation: In the future, preferably combine into one measure stratified for adult and pediatric (including home HD if possible).For all measures of dialysis adequacy (frequency, method, and results), the Committee recommends switching to measuring standard Kt/V so that all patients can be combined regardless of frequency and one measure can be stratified by adult and pediatric. What would be required to move to that measurement? Would a standard Kt/V accommodate home patients who may have adequacy measured on a weekly basis? Is there a standard Kt/V threshold that would apply to all patients and all frequencies?
Developer Follow-up: The revised measure specifications were submitted.
The CTEP did not discuss stdKt/V as an option for measuring dialysis adequacy. In addition, based on our literature review, evidence that evaluates the impact of dialysis adequacy is based on spKt/V. This has implications in identifying a cut-off for stdKt/V in the pediatric population. Based on these points, we propose that the current measure remain as developed by the TEP with the use of spKt/V. In addition, we suggest that the use of stdKt/V be re-evaluated with a future TEP when more evidence regarding its use in the pediatric population becomes available.

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 the exclusion was due to lack of data, not based in the clinical evidence. The Committee discussed that standard Kt/V would allow all patients regardless of frequency to be included in the measure of minimum adequacy.

2. Scientific Acceptability of Measure Properties: C-6; P-13; M-1; N-0
(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. The method is associated with frequency of dialysis, but this measure is just about the method for a single session, so either method (UKM, Daugirdas) in numerator is acceptable. 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; 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-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: The needed data elements are easily collectable and reliable through the proposed Crownweb system.

1421 Method of adequacy measurement for pediatric hemodialysis patients
Public and Member Comment Comments included: • support of this measure; • harmonize or combine with adult measures; and • question whether it meets NQF's criteria for Importance to Measure and Report. The numerator is harmonized with the adult measure (#0248). It is important to measure separately in the pediatric population and although that could be accomplished in one stratified measure, the steward has opted to maintain two separate measures. The Steering Committee addressed the issues raised regarding Importance to Measure and Report while evaluating the measure as noted above and in Overarching Issues. The Committee upheld its recommendation for endorsement because pediatric ESRD care is a new area of performance measurement and there was less than optimal performance. This will be re-evaluated at the time of endorsement maintenance. The developer was asked to clarify whether home patients should be included in all the measures. Developer Response: The CMS technical expert panel recommended excluding home hemodialysis patients from this measure because this population has not been thoroughly evaluated. CROWNWeb will collect data on these patients to allow for future evaluation and reconsideration of this exclusion.

1423 Minimum spKt/V for pediatric hemodialysis patients

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

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/Vgreater than =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 hemodialys isl ess than 90 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, MD 21244

Steering Committee Recommendation for Endorsement: Y-11; N-9
Rationale: The rationale for endorsement is that a minimal level for HD adequacy is important in pediatric patients.
The rationale against endorsement questions the evidence for setting the minimal dose at 1.2 (perhaps it should be higher for pediatric patients) and the questions the use of spKt/V for different frequencies of dialysis.

If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up: Related measure 0250: Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
Recommendation: Specifications should be completely harmonized except for frequency of dialysis in pediatric measure of 3-4x/wk.
In the future, for all measures of dialysis adequacy (frequency, method, and results), the Committee recommends switching to measuring standard Kt/V so that all patients can be combined regardless of frequency and one measure can be stratified by adult and pediatric. What would be required to move to that measurement? Would a standard Kt/V accommodate home patients who may have adequacy measured on a weekly basis? Is there a standard Kt/V threshold that would apply to all patients and all frequencies?
Developer Follow-up: The CTEP did not discuss stdKt/V as an option for measuring dialysis adequacy. In addition, based on our literature review, evidence that evaluates the impact of dialysis adequacy is based on spKt/V. This has implications in identifying a cut-off for stdKt/V in the pediatric population. Based on these points, we propose that the current measure remain as developed by the TEP with the use of spKt/V. In addition, we suggest that the use of stdKt/V be re-evaluated with a future TEP when more evidence regarding its use in the pediatric population becomes available. Measure has not been revised.

1. Importance to Measure and Report: Y-13; N-7
(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)
Rationale: Although it is questionable whether 1.2 is the correct target and whether it's 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 minimum may become the standard. At present there are opportunities for improvement in this area because a number of pediatric patients are 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 expert Committee members stated that the goal was to include as many patients as possible in the denominator so patients dialyzing 3-4 days week were included in the denominator. Another Committee member commented that that is 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 the patient has better urea removal. A pediatric expert on the Steering Committee stated that the younger patients having dialysis 4x/wk and they want them to meet the 1.2 with each treatment because they need it (actually represents different standard in one measure). Reliability of the spKt/V element was demonstrated. Only face validity addressed; systematic assessment not reported.

3. Usability: C-4; P-12; M-4; N-0
(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 is easily understood by multiple audiences.

4. Feasibility: C-7; P-10; M-3; N-0

1423 Minimum spKt/V for pediatric hemodialysis patients
(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 is already in place and iscommonly used to report to CMS. The feasibility of measurement without error is high.
Public and Member Comment Comments included: • support of this measure; • use standard Kt/V and combine with adult measures; and • include home hemodialysis patients. The Steering Committee previously recommended using standard Kt/V as noted above but the developer indicated that was not yet possible. At this time, it would not be appropriate to combine with the adult measure because pediatric patients often require different frequencies of dialysis. The developer was asked to clarify whether home patients should be included. Developer Response: Patients with "Primary Dialysis Setting"= "Home" on the last day of the study period will be excluded. The CMS technical expert panel recommended excluding home hemodialysis patients from this measure because this population has not been thoroughly evaluated. CROWNWeb will collect data on these patients to allow for future evaluation and reconsideration of this exclusion.

1425 Measurement of nPCR for pediatric hemodialysis patients

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

Description: Percentage of pediatric (less than18 years old) in-center ~~HD~~ hemodialysis 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.~~[I1]
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, MD 21244

Steering Committee Recommendation for Endorsement: Time-Limited Y-12; N-8
Rationale: The rationale for endorsement is that this measure of nutrition, nPCR, can be easily calculated and can provide important information about the nutrition of pediatric HD patients. Its use can result in ~~improved~~ improved long-term outcomes in pediatric patients. The rationale against endorsement 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?
Developer Response: We thank the NQF Steering Committee for the opportunity to correct this. The denominator should read: "Number of all pediatric (<18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis)".
Steering Committee Follow-up:
Developer Follow-up: The revised measure specifications were submitted.

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 is 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 target values or interventions to change them, so it raises the question of whether they are 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-0
(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 ratings are primarily based on the specifications (in the future, the Steering Committee will be instructed that the highest rating for untested measures is minimal). 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-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: The data are routinely generated, and the calculation of the measure is similar to that of the measure of frequency of measuring Kt/V. Facilities already report the data electronically.

Public and Member Comment
Comments included:
- general support of this measure;
- question of whether it meets NQF's criteria for Importance to Measure and Report; and
- limit to adolescent patients.

The Steering Committee addressed the issues raised regarding Importance to Measure and Report while evaluating the measure as noted above and in Overarching Issues. The Committee upheld its recommendation for endorsement because pediatric ESRD care is a new area of performance measurement and there was less than optimal performance. This will be re-evaluated at the time of endorsement maintenance. The developer was asked to clarify whether home patients should be included.
Developer Response:
Although evidence for nPCR targets is limited to adolescent patients, this measure is for the process of monitoring nPCR and it uses the same data needed for the adequacy measure. The CMS technical expert panel recommended excluding home hemodialysis patients

1425 Measurement of nPCR for pediatric hemodialysis patients
from this measure because this population has not been thoroughly evaluated. CROWNWeb will collect data on these patients to allow for future evaluation and reconsideration of this exclusion.

1424 Monthly hemoglobin measurement for pediatric patients

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

Description: Percentage of all pediatric (less than18 years) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin.
Numerator Statement: Number of pediatric (less than18 years old) in-center hemodialysis, home 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) in-center hemodialysis, home hemodialysis and peritoneal dialysis patients.
Exclusions: ~~Patients who are not in the facility for the entire calendar month.~~None.
Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. Measure may be displayed separately for in-center hemodialysis patients, home hemodialysis patients, and peritoneal hemodialysis patients.
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, MD 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 warrant the use of this measure.

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 warrant 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-0
(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 was demonstrated for "Hb ≥ 9", but measure is based on Hb value and collection date. Face validity was mentioned, but there is no description of systematic assessment.

3. Usability: C-18; P-2; M-; N-0
(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-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: Data for the measure are in the process of being collected via the ESRD CPM, and units are familiar with the procedure.

Public and Member Comment
Comments included:
- support of the measure;
- question of whether it meets NQF's criteria for Importance to Measure and Report; and
- include CKD stage 3 and 4 patients and home hemodialysis and peritoneal dialysis patients

The Steering Committee addressed the issues raised regarding Importance to Measure and Report while evaluating the measure as noted above and in Overarching Issues. The Committee upheld its recommendation for endorsement because pediatric ESRD care is a new area of performance measurement and there was less than optimal performance. This will be re-evaluated at the time of endorsement maintenance. The Committee asked the measure developer to review the specifications for inclusion of home patients or provide rationale for their exclusion. The measure was not developed or submitted to include the CKD population and would require additional development/testing.
Developer Response:
The measure developer agreed to include home hemodialysis and peritoneal patients and submitted revised specifications as indicated above and in the specifications Table in Appendix A.

1430 Lower limit of hemoglobin for pediatric patients

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

Description: Percentage of pediatric (less than18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients, with ESRD greater than or equal to =3 months, who have a mean hemoglobin less than10 g/dL for a 3 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 3 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 to 3 months

Exclusions: Patients on dialysis less than 3 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, MD 21244

Steering Committee Recommendation for Endorsement: Final: Y-12; N-7; A-1; Initial: Y-18; N-2 with Conditions

Rationale: Anemia is related to morbidity and mortality and how patients feel and function. The provided data indicated that 14-19% of pediatric patients had hemoglobin levels < 10 g/dl in 2007.

If applicable, Conditions/Questions for Developer: Conditions: 1) exclude patients w/sickle cell anemia, 2) numerator: number of patients with Hb < 10 for each of 3 months (Y-13; N-7)

Developer Response: Arbor Research and the Pediatric Clinical Technical Expert Panel (C-TEP) discussed the points recommended by the NQF Steering Committee:

"A. In regards the exclusion of patients with sickle cell disease, the Pediatric C-TEP generally agrees with this suggestion since achievement of the minimum hemoglobin target is more difficult in these patients. The C-TEP also recognizes that facilities that dialyze fewer pediatric patients are more likely to be impacted by patients with sickle cell disease Given that published data suggests that only a very small number of pediatric patients have a diagnosis of sickle cell disease (0.3% of dialysis patients, NAPRTCS 2008 Annual Report, https://web.emmes.com/study/ped/annlrept/annlrept.html), the burden of data collection should be balanced with the measure improvement gained with exclusion of these patients. With all these points in mind, the C-TEP proposes to move forward with the measure and that exclusion of sickle cell patients will be submitted as a measure maintenance step as soon as data for this diagnosis are available from CMS data.

B. In regards the definition of the lower limit for Hb, the NQF suggested the use of a persistently low Hb level below 10g/dL for the 3 month reporting period rather than the original measure which uses a 3 month mean below 10g/dL. Although the C-TEP recognizes that patients who start hemodialysis with very low hemoglobin levels may have difficulty in achieving the Hb target, the requirement for inclusion of patients with ESRD of 3 months mitigates this concern. In addition, the C-TEP does not support this proposed revision for the following reasons: a. In facility-level analyses comparing achievement of hemoglobin levels based on persistently low Hb levels as suggested by the NQF vs the original proposed measure, the mean facility-level percent of patients missing this target was 3.3% of facilities compared to 14.9% with the latter target. This suggests a marked reduction in the sensitivity of the measure in capturing pediatric patients with anemia; b. Literature providing evidence for morbidity and mortality associated with low hemoglobin levels are based on mean values rather than on persistently low hemoglobin levels; c. Existing policies, including the use of the Quality Incentive Payment utilizes mean hemoglobin levels; d. Requiring a persistently low hemoglobin level to define this measure may lead to substandard care as clinicians may delay appropriate clinical response; e. Finally, requiring persistently low Hb levels creates a measure that is more likely to identify patients with ESA resistance anemia rather than in identifying patients who would benefit from more aggressive anemia treatment."

Steering Committee Follow-up: The majority of the Steering Committee accepted the developer's response. However, the Committee remained somewhat divided about viewing this as a measure indicating overall management of anemia (percent with Hb <10 using the mean over 3 months) vs. changing it to a measure of patients with persistently low Hb (percent with Hb <10 for each of 3 moths)..

Developer Follow-up:

1. Importance to Measure and Report: Final: Y-17; N-1; Initial: 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 that 14-19% of pediatric patients had hemoglobin levels < 10 g/dl in 2007; more recent data were not provided. Although there is little to no evidence to support a specific value for the pediatric population, there is no evidence that it should be different from the adult measure.

2. Scientific Acceptability of Measure Properties: Final: C-7: P-9; M-2; N-0; Initial: Did not vote on rating because of recommended

1430 Lower limit of hemoglobin for pediatric patients
changes. *(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)* Rationale: 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 3 months (Y-13; N-7) in order to identify persistent anemia. There is a need for action when hemoglobin is <10, and a performance measure should identify when action is inadequate. Other Committee members advocated for the average over 3 months as specified because the measure aggregates data from all patents and is an indicator of how well anemia is managed overall; it is not intended for clinical management individual patients. The 3-month average takes into account biologic variability. The proposed change focuses on outliers versus overall management. Additionally, a measure using the average would be harmonized with the adult measure. When asked, the developer indicated that its TEP did not discuss persistently low hemoglobin.
3. Usability: Final: C-8: P-8; M-2; N-0; Initial: Did not vote on rating because of recommended changes *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: A performance measure of mangement of anemia is useful for quality improvement.
4. Feasibility: Final: C-12: P-4; M-2; N-0; Initial: Did not vote on rating because of recommended changes. *(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 required in CROWNweb. The developer indicated that the proposed change was possible with the data available, but ultimately did not agree with the condition.
Public and Member Comment Comments included: • support of this measure; and • include CKD stage 3 and 4 patients The measure was not developed or submitted to include the CKD population and would require additional development/testing. The Steering Committee asked the measure developer to clarify whether home dialysis patients are included in the measure. Developer Response: The measure developer clarified that home hemodialysis patients are included and submitted revised specifications as indicated above and in the specifications in Appendix A.

1433 Use of iron therapy for pediatric patients

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

Description: Percentage of all pediatric (less than18 years old) in-center hemodialysis, home 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 than 20% during the study period.
Denominator Statement: All pediatric (less than18 years old) in-center hemodialysis, home 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 was 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~~ 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 (Consolidated Renal Operations in a Web Enabled Network)
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 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 does 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?
Developer Response: "Measurement of ferritin levels and tranferrin saturation levels represent different approaches to the assessment of iron stores. Both values are necessary for the proper assessment of iron status, and for practical reasons, especially for pediatric patients on peritoneal dialysis, a single blood draw is commonly used for the measurement of both values. In addition, there is no evidence that iron therapy is beneficial for patients in whom transferrin saturation levels are low but ferritin levels are markedly elevated. Nevertheless, if the ferritin levels and transferrin saturation levels are not obtained simultaneously, then the appropriate clinical action still applies. Thus, in response to the NQF comment, it is not critical to obtain simultaneous values for ferritin and TSAT; however, both measures are necessary prior to the initiation of iron therapy. We suggest revising the measure description to the following:
'Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin <11.0 g/dL and in whom serum ferritin concentration was <100 ng/ml and TSAT<20% who received IV iron or were prescribed oral iron within the following three months'
Relatedly, we suggest revising the denominator to the following:
'All pediatric (<18 years old) hemodialysis and peritoneal dialysis patients in the facility for the entire three-month reporting period with hemoglobin <11 g/dL and in whom serum ferritin was <100 ng/mL and TSAT<20% during the three month study period.'
The numerator remains as:
'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 <100 ng/mL and transferrin saturation (TSAT) <20% during the study period.' "
Steering Committee Follow-up:
Developer Follow-up: The revised measure specifications were submitted.

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 does 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 suggest 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 advocated for this measure because it emphasizes 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-0
(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 ratings are primarily based on the specifications (in the future, the Steering Committee will be instructed that the highest rating for untested measures is minimal). Measure specifications are precise. Reliability of data elements for lab values were presented, but there was nothing about iron therapy, the central topic of the measure; therefore, this measure will be considered untested. Face validity was mentioned, but a description of systematic assessment was not provided. Facilities could meet measure by prescribing oral iron, even if it is not taken or responsive or is inappropriate for HD patients, whichs call into question the measure's validity as a quality

1433 Use of iron therapy for pediatric patients
indicator. What happens if ferritin and TSAT values are not simultaneous, i.e., excluded from denominator?
3. Usability: C-3; P-14; M-3; N-0 *(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-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: Data generated from routine care and reported electronically. Is there an unintended consequence of overuse of iron therapy?
Public and Member Comment Comments included: • support of the measure; • include CKD stage 3 and 4 patients; and • include home hemodialysis and peritoneal dialysis patients. The measure was not developed or submitted to include the CKD population and would require additional development/testing. The Steering Committee asked the measure developer to clarify whether home dialysis patients are included in the measure. Developer Response: The measure developer agreed to include home hemodialysis patients and submitted revised specifications as indicated above and in the specifications in Appendix A.

1438 Periodic assessment of post-dialysis weight by nephrologists

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

Description: The proportion of in-center hemodiallysis, home hemodialysis, and peritoneal dialysis patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month, ~~.~~ irrespective of whether or not a change in post dialysis weight prescription was made.

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 irrespective of whether or not a change in post dialysis weight prescription was made.

Denominator Statement: ~~Number of patients~~ All adult and pediatric in-center ~~an outpatient dialysis facility undergoing chronic maintenance~~ hemodialysis, home hemodialysis, and peritoneal dialysis patients. ~~(HD)~~.

Exclusions: None.

Adjustment/Stratification: No risk adjustment necessary N/A No stratification is required for this measure. However, the measure could be displayed for all patients or stratified to show results separately for pediatric and adult patients. Simillarly, the measure could be displayed separately for in-center hemodialysis patients, home hemodialysis patients, and peritoneal dialysis patients.

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

Final: Y-19; N-0; A-1; Initial: Y-20; N-0 with Condition

Rationale: The Committee thought that some measure to highlight the importance of fluid and weight management was necessary, and this is the best measure at this time because of 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?

Developer Response: "Arbor Research/UM-KECC and the Pediatric C-TEP agree that the pediatric population should be included in this measure for reasons summarized in the measure information form. In addition, fluid assessment and weight monitoring are even more critical in the pediatric population because of linear growth and gain in body mass. The C-TEP notes that although the proposed measure requires reporting of a monthly prescription for post-dialysis weight, this does not denote that actual monthly assessments are performed. Nevertheless, the Pediatric C-TEP believes that this measure encourages good clinical practice and can potentially be used to identify patients who are not experiencing weight gain. Finally, the Pediatric C-TEP recommends that this measure be calculated separately for the pediatric population rather than as a pooled measure with the adult population.

The adult Fluid Weight Management (FWM) Clinical TEP that was organized by Arbor Research/UM-KECC (contractors for the CMS) and charged with the task of evaluating and proposing potential measures in the area of fluid-weight management recently deliberated on the issue of extending measure 1438 to the pediatric population in response to the recent NQF vote supporting the time-limited endorsement of this measure.

There was consensus among the FWM C-TEP members with regards to extending the implementation of this measure to the pediatric population. However, it must be emphasized that this recommendation was based on the collective clinical experience of the FWM C-TEP supporting the notion that monitoring volume on a regular basis in the pediatric population is likely to be a worthwhile endeavor, consistent with good clinical practice. It is therefore an opinion-based recommendation at this time that has not been subjected to the rigor of a formal review of evidence.

Based on the conversation at the Steering Committee meeting, it was our understanding that the suggestion to remove the word 'new' from the description was rescinded. We note that the word 'new' prescription should be retained in view of the TEP's reasoning that it will likely push the requirement for a formal monthly prescription by dialysis facilities.

To address the Steering Committee's concerns, we could add the phrase 'irrespective of whether or not a change in post dialysis weight prescription was made' in the description and other areas to be consistent and remove any ambiguity in this regard."

Steering Committee Follow-up: The Steering Committee accepted the developer's response.

Developer Follow-up: The revised measure specifications were submitted.

1. Importance to Measure and Report: Final: Y-18; N-0; Initial: 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 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 at this time because of 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 why the measure should not apply to pediatric patients. When the Steering Committee asked the developer if the measure should also apply to home hemodialysis patients, the comment was made that monthly might not be appropriate.

2. Scientific Acceptability of Measure Properties: Final: C-8: P-7; M-3; Initial: C-9; P-8; M-2; N-0

(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f.

1438 Periodic assessment of post-dialysis weight by nephrologists
Meaningful differences; 2g. Comparability; 2h. Disparities) Rationale: The ratings are primarily based on the specifications (in the future, the Steering Committee will be instructed that the highest rating for untested measures is minimal). The specifications for a "new" post-dialysis weight prescription may imply that the prescription must be changed; however, 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; therefore reliability and validity are no known.
3. Usability: Final: C-9: P-9; M-0; N-0; Initial: 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: Final:C-9: P-9; M-0; N-0; Initial: C-7; P-8; M-5; 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: Data would be collected and acted upon as part of process of care and will be included in the CMS data system.
Public and Member Comment Comments included: • general support of the measure; • include home hemodialysis patients; and • measure for physicians rather than facilities. The Steering Committee asked the measure developer to clarify whether home hemodialysis patients are included in the measure. The measure was submitted as a facility-level measure and the Committee thought that it was appropriate at the facility level where patients are receiving dialysis treatments. Developer Response: The measure developer clarified that home hemodialysis patients as well as adult and pediatric patients are included and submitted revised specifications as indicate above and in the specifications in Appendix A.

1454 Proportion of patients with hypercalcemia
For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings
Description: Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL. Numerator Statement: Number of patients in the denominator with 3-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) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the ~~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 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, MD 21244
Steering Committee Recommendation for Endorsement: Final: Y-11; N-8; A-1; Initial: Y-18; N-2 with Conditions 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: number of patients with total uncorrected Ca > 10.2 for each of 3 months (Y-13; N-7) Developer Response: "The Arbor Research investigators appreciate the NQF Steering Committee suggestion and have discussed it with the Mineral and Bone Disorder Clinical Technical Expert Panel (C-TEP) who contributed to the development of the proposed measure. Published studied assessing the association of serum calcium with clinical outcomes were largely based on single calcium levels and not on persistently high calcium levels. However, the C-TEP proposed measure only included patients with a three-month rolling average of total uncorrected serum calcium > 10.2 mg/dl. This conservative approach was chosen to identify patients who may be more likely to experience poor clinical outcomes due to the prolonged exposure to elevated serum calcium levels over time. The proposed revision would identify patients who are consistently exposed to very high calcium levels over the prior three months. However, the C-TEP members had the opinion, supported by the data reported below, that only very few patients would meet this criterion, since it less likely that patients have high calcium for three consecutive months. This was confirmed using Crown web data collected from March 2010 through May 2010: while 6,284 patients (3%) met the requirements for the proposed measure, only 1,584 patients (0.8%) met those for the revised measure. Similarly, the number of facilities that would be flagged based on given % of patients meeting the measure criteria decreased dramatically (see Table 1 below). For example, 780 facilities had 5% or more of patients meeting the proposed criteria, while only 113 had ≥5% of patients meeting the revised criteria. Based on these data, the C-TEP felt that the proposed change may negatively impact the quality of care delivered, since only very few patients with persistently high calcium over a three-month period would be included." Steering Committee Follow-up: The majority of the Steering Committee accepted the developer's response. However, the Committee remained somewhat divided about viewing this as a measure indicating overall management of hypercalcemia (Ca > 10.2) using the mean over 3 months vs. changing it to a measure of patients with persistently high calcium. Developer Follow-up:
1. Importance to Measure and Report: Final: Y-16; N-2; Initial: 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, i.e., 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: Final: C-4: P-11; M-3; N-0; Initial: Did not vote on rating because of recommended changes. *(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 suggested that the denominator be limited 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 3 months (Y-13; N-7), which is consistent with using trends for patient management. A patient could have a decreasing trend and still be included in the numerator. The developer confirmed that

1454 Proportion of patients with hypercalcemia
the change would be possible with the data. Other Committee members advocated for the average over 3 months as specified because the measure aggregates data from all patents and is an indicator of overall management; it is not intended for clinical management individual patients.
3. Usability: Final: C-7: P-9; M-2; N-0; Initial: Did not vote on rating because of recommended changes. *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Identifying erformance related to managng hypercalcemia is useful for quality improvement.
4. Feasibility: Final: C-9: P-7; M-2; N-0; Initial: Did not vote on rating because of recommended changes. *(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 required in CROWNweb. The developer indicated that the proposed change was possible with the data available, but ultimately did not agree with the condition.
Public and Member Comment Comments included: • support of the measure; and • include home hemodialysis patients. The Steering Committee asked the developer to clarify the inclusion of home hemodialysis patients Developer Response: The measure developer clarified that home hemodialysis patients are included and submitted revised specifications as indicated above and in the specifications in Appendix A.

Table 1. Number (%) of facilities that would be flagged, by % of patients meeting the measure criteria (proposed vs. revised)

	Number (%) of facilities where measure is met			
Facility % of patients meeting criteria	≥5%	≥10%	≥15%	≥20%
Proposed criteria (% of patients with 3 month rolling average Ca > 10.2)	780 (23%)	235 (7%)	66 (2%)	14 (< 1%)
Revised criteria (% of patients with Ca > 10.2 in all three months)	113 (3.4%)	15 (< 1%)	4 (< 1%)	3 (< 1%)

1463 Standardized hospitalization ratio for admissions

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

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 The denominator of the SHR uses expected hospital admissions calculated from a Cox model (Cox, 1972) as extended to handle repeated events (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). For computational purposes, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and computational methodology as developed in Liu, Schaubel and Kalbfleisch (2010). A stage 1 model is first fitted to the national data with piecewise-constant baseline rates stratified by facility; hospitalization rates are adjusted for patient age, race, sex, diabetes, ethnicity, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The linear predictor for each patient based on the regression coefficients in the stage 1 model is used to compute a risk adjustment factor that is then used as an offset in the stage 2 model. N/A
Level of Analysis: Facility/Agency
Type of Measure: Outcome
Data Source: Public health data/vital statistics; Electronic Health/Medical Record Data for the hospitalization measures are derived from an extensive national ESRD patient database, which is largely derived from the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs).
Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Final: Y-17; N-2; A-1; Initial: Y-18; N-2 with Conditions
Rationale: The measure addresses a National Priorities Partnership (NPP) goal, and although 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 1 rather than 3 years 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?
Developer Response: "After consulting with and considering recommendations from Arbor Research/UM-KECC, CMS has decided to remove race and ethnicity from the SHR risk model. If needed, analyses for the SHR model without race and ethnicity can be provided at a later date.
It was our intent to have SHR (Admissions) approved as a measure that can be calculated over any given time period within the range of 6 months to 3 years. The period of time depends on the purpose of the statistic and would have a minimum period of 6 months. For example, the SHR has been reported both for 1-year and 3-year periods in the Dialysis Facility Reports in order to help facilities identify persistent patterns. The 1-year values allow for an assessment of changes over time, while the 3-year value gives a summary value and provides more stability for very small facilities. The 1-year SHR is a stable measure as indicated by its high correlation with the 3-year SHR (?=0.85, 2006-2008 data). Similarly, the 6-month SHR is relatively stable as indicated by its high correlation with the 1-year SHR (?=0.88, 2008 data).
The source is the CMS Medicare Claims data."
Steering Committee Follow-up: The Steering Committee accepted the developer's response.
Developer Follow-up: The revised measure specifications were submitted.

1. Importance to Measure and Report: Final: Y-17; N-1; Initial: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 measure in the ESRD population.
Several Committee members suggested that hospitalization was not under the control of ESRD facilities or clinicians. Other Committee members stated 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: Final: C-5: P-10; M-3; N-0; Initial: C-7; P-12; M-1; N-0
(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 3-year time period, and the developer indicated that 1 year was acceptable. NQF

1463 Standardized hospitalization ratio for admissions
criteria indicate that race and ethnicity (often associated with disparities in care) should not be used as factors in risk models.
3. Usability: Final: C-6: P-11; M-1; N-0; Initial: C-8; P-9; M-3; N-0 *(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing measures)* Rationale: Usability was not demonstrated. Several Committee members questioned actionability by providers of ESRD care. Other Committee members noted that dialysis care and 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: Final: C-12: P-6; M-0; N-0; Initial: C-12; P-6; M-2; 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: The measure is based on claims data and requires no additional data collection.
Public and Member Comment Comments included: • general support of the measure; • include only hospitalizations related to dialysis treatment; and • question the methodology and calculation. The Steering Committee concluded that it would be difficult to reliably identify only hospitalizations related to dialysis treatment. Regarding the review of the methodology calculation, the Committee accepted the calculation and risk model performance metrics as described by the developer in the measure submission and supplemental materials.

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure(title will be changed to: Bloodstream Infection in Hemodialysis Outpatients)

For More Information: Detailed Measure Specifications; Complete Measure Submision; Meeting/Call Proceedings

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 1 calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient.
Denominator Statement: Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first 2 working days of the month.
Exclusions: Patients receiving inpatient hemodialysis are excluded.
Adjustment/Stratification: other Simple Stratification Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, permanent central line, and temporary central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (i.e., AV fistula less than AV graft less than permanent central line less than temporary central line). During denominator collection (see URL below), the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data. Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters).
Details of stratified measures:
1. BSI rate in CVC (central venous catheter) patients = the numerator and denominator below times 100
1a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and ""Port access device".
2. BSI rate in AVG (arteriovenous graft) patients = the numerator and denominator below times 100
2a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119.
3. BSI rate in AVF (arteriovenous fistula) patients = the numerator and denominator below times 100
3a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device".
3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119.
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, GA 30333

Steering Committee Recommendation for Endorsement: Y-13; N-7; Initial: pending compariosn of competing measures
Rationale: Patients receiving hemodialysis are at risk for bacteremia, particularly related to vascular access so it is an improtant and useful measure.

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 2 days of the month miss incident dialysis patients who have the highest risk of catheters for access, infections, and readmission to the hospital?
Developer Response: "1. This statement was included under the 'Numerator Time Window' measure specification. The intent of specifying 'during the month that the outpatient unit is performing surveillance' was to indicate how numerator and denominator data correlate with one another in time, not that data collection is not continuous. Numerator data are collected and reported continuously; denominator data are collected and reported monthly. NHSN requires facilities to report data for a minimum of 6 months per year. Facilities are encouraged to exceed that minimum duration of reporting and in some cases are legislatively mandated to do so.
2. A patient who is new to a particular dialysis facility would be excluded from a denominator if they entered the facility sometime after the first week of the month. However, assuming they remain in the facility, they would be captured in the following month's denominator. It is important to remember that all patient events are reported regardless of when a patient enters the facility. Thus, a high-risk or

incident patient who enters a facility mid-month and develops a bloodstream infection during that month will be reported in the numerator data. Although that specific patient may not have been present at the beginning of the month, the bloodstream infection rate calculated for that month will still reflect the patient's event. So these infections would not be 'missed' or undercounted. The denominator used is a snapshot in time and stratified by vascular access type. In any given week (represented by the 2-day snapshot), the proportion of patients with each vascular access type does not markedly differ. It is possible that rates based on patient-month denominator data do not perfectly correlate with rates calculated on the basis of patient-days. For example, rates in the highest risk vascular access strata could be slightly over-estimated: (a) if incident patients come in with a catheter and routinely have the catheter removed and switch to another vascular access type in 0-3 weeks (i.e., by the time they are counted in the next month's denominator), (b) if those patients have a uniquely high frequency of infection or other events during those initial 0-3 weeks, and (c) if the facility has a high frequency of new admissions every month that represent this type of incident patient. This series of events seems unlikely to occur on a regular basis, in part because catheter patients who develop a bloodstream infection or other access complication are unlikely to quickly transition to a permanent access (i.e., combination of (a) and (b) happening in the same patient is rare). This hypothetical effect should also be mitigated by the fact that catheter patients have the highest likelihood of death, hospitalization or other events that would reduce their overall exposure time within the outpatient dialysis facility. I.e., a catheter patient who is present on the first 2 days of the month and counted in the denominator is least likely to contribute a full patient-month of observation-time.

When NHSN infection rates based on 100 patient-month denominators are roughly translated (by dividing by 3) to rates per 1000 catheter-days, they are comparable to figures reported in the literature based on measured catheter-day denominators, suggesting that use of patient-month denominators does not introduce a substantial bias into rates for the catheter group. The alternative would be to count all patients who receive dialysis on each day by vascular access type, adding substantially to the burden of data collection without clear benefit.

Colorado just released preliminary data submitted to NHSN from dialysis facilities under their reporting mandate. I believe someone from the committee had asked about this, so I am sharing. A link to the full report is below; only certain sections pertain to dialysis reporting. Of note, Colorado has decided to publicly report the NHSN access-related BSI (what they call 'AAB') measure. I know there are concerns about additional reporting burden for that measure in comparison to the NHSN BSI measure. However, I did want to highlight several qualities of the NHSN access-related BSI measure for the committee to consider: 1. Access-related BSI (ARB) is a measure that has meaning to clinicians because it is viewed as a potentially preventable subset of BSI. 2.This measure is often the focus of prevention studies—i.e., interventions such as improvements in central line or other vascular access care are often evaluated using the ARB measure. This is where we would expect to see the greatest impact. 3. As noted above, Colorado has chosen to publicly report this measure. 4. As a subcategory of BSI, ARB is not independently reported. It is based upon a single variable response, thus the incremental burden of reporting ARB is small.

We believe there is great value in collecting and evaluating both the ARB and BSI measure for quality improvement. These measures are collected together and complement one another. While the BSI measure is more objective and simple, it has been our experience that the minimal added burden involved in collecting the variable to make the ARB determination is outweighed by this measure's relevance to clinicians / users and to quality improvement efforts.

http://www.cdphe.state.co.us/hf/PatientSafety/HFAcquiredInfectionsReport11.pdf"

Steering Committee Follow-up: NQF and the ESRD Steering Committee requested that CMS and CDC collaborate on submitting one measure of bacteremia in ESRD patients, stratified by type of vascular access, that will meet both government agencies' needs and for which data could eventually be exchanged electronically between the two agencies. For now, at a minimum, facilities should be able to submit the same data to both agencies.

Related Measure: PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure

Why is this measure for ESRD bloodstream infection different than CDC's recently updated measure?

Developer Follow-up: CMS and CDC agreed to work together on one measure; however, they were not able to accomplish identifying cross-walked specifications for use with CROWNweb in the time allowed for this project. CMS agreed that it could use the CDC definitions as long as the NHSN form or data system is not required because ESRD facilities are required to submit data through CROWNweb. NQF clarified that although detailed measure specifications often identify specific data collection tools (e.g., CMS' MDS for nursing home measures), endorsed measures can be implemented with different data collection tools and systems as long as the data definitions in the endorsed measure and measure construction logic are followed. The CDC also agreed that the measure does not require use of the NHSN data tools and systems and agreed to clarify definitions if needed. If #1460 is endorsed, CMS will implement the measure specifications into its CROWNweb system by a date yet to be determined. CMS and CDC agreed to pursue data sharing arrangements so that ESRD facilities could submit data to either agency. Both CROWNweb and NHSN have capacity for batch submission of data.

Positive blood culture was defined as a blood culture that results in growth of 1 or more organisms.

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure(title will be changed to: Bloodstream Infection in Hemodialysis Outpatients)

This measure has always been distinct from the inpatient CLABSI measure for several reasons.

1) Surveillance not primarily performed by Infection Preventionists or physicians

Measures in the dialysis event module were developed for use by dialysis care personnel in outpatient hemodialysis facilities. In inpatient settings, infection control professionals typically conduct case-finding and apply CLABSI case definitions, sometimes in conjunction with physicians and microbiologists. These professionals are not routinely available in outpatient dialysis settings to apply complex case definitions or assess clinical infection data. Measures were selected in a way to maximize ease and consistency of reporting in this setting using simple, objective event descriptions that would not require infectious disease or other expertise to make determinations. For example, the first highlighted section (2. Definitions of CLABSI) describes the definition of a primary BSI, "not secondary to an infection meeting CDC/NHSN criteria at another body site". This initial step requires the user to be familiar with a range of CDC / NHSN healthcare-associated infection (HAI) definitions just to be able to distinguish a primary from secondary BSI. In our opinion, this level of complexity would be unacceptable for users in dialysis settings, particularly since they would not be routinely performing surveillance for these other HAI types and thus, would not be familiar with the definitions used as exclusion criteria. Diagnoses made in outpatient settings may also lack the evidence (or documentation of evidence) necessary to meet rigorous definitions for CLABSI or CLABSI exclusion criteria, impacting the feasibility of use of these definitions beyond inpatient settings.

2) Hemodialysis access types other than central lines

The CLABSI measure only records central line-associated BSI. In hemodialysis settings, BSI rates among patients with fistulas or grafts are also of interest. Thus, a measure that is not restricted to one vascular access type is needed.

3) Burden of denominator collection

Denominator collection for the CLABSI measure requires measurement of central line days, which is overly burdensome for this setting, which has a more stable patient population compared to inpatient ward or ICU settings.

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-0

(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, infections, and readmission to the hospital. In response to questions about the specifications, the developer clarified that the denominator statement of patients on first 2 days of month is just to minimize the burden of data collection, but all bloodstream 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 bloodstream 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-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: 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.

Public and Member Comment

Comments received were in support of the measure. The developer was asked to clarify the inclusion of home hemodialysis patients.

Developer Response:

Home hemodialysis patients were not included in CDC's original measure proposal and our justification for excluding them from the measure is (1) we lack practical experience outside of applying the measure to patients who are dialyzed in dialysis facilities—capturing

1460 National Healthcare Safety Network (NHSN) bloodstream infection measure(title will be changed to: Bloodstream Infection in Hemodialysis Outpatients)
positive blood cultures and other measure information needed from home hemodialysis patients could be operationally problematic, and (2) risk exposure and prevention strategies are not necessarily equivalent in the two settings (dialysis facilities and home dialysis), so combining the two patient populations in a singled summary metric may be misleading as a quality measure and fall short as a guide to prevention and quality improvement.. CDC readily acknowledges that bloodstream infections are a clinical and public health problem in the home dialysis patient population, and in the future we are likely to extend our surveillance and prevention activities to that population. While we do not have a timetable for this extension, identifying or developing appropriate outcome measures will be a high priority when the work begins in earnest.

Evaluation Summary—Candidate Consensus Standards Not Recommended for Endorsement

The summary of the comments and subsequent actions can be found in the evaluation summary tables below.

1426 Assessment of iron stores
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 (greater than =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 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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
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 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.
Public and Member Comment One comment received from the steward on its rationale that the measure focus is important because assessment of iron stores improves the management of anemia. The Steering Committee did not identify any new information on which to reconsider its decision.

1431 Measurement of iron stores for pediatric patients
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 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, MD 21244
Steering Committee Recommendation for Endorsement: Y-9; N-11 Rationale: The rationale for endorsement is primarily that pediatric measures are needed. The rationales against endorsement are the same as those for for the adult measure, i.e., obtaining lab values is not proximal to desired outcome, and measure of Hb values is a better measure of anemia management.
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 measurement of 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-0 *(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 currently collected via CMS data system and can be easily used in the measure.
Public and Member Comment One comment was in agreement with the Committee's decision and one comment was from the steward on its rationale for measuring iron stores noting that erythropoietin therapy will not result in an increase in hemoglobin if iron stores are deficient. However, they indicated they would work on revising this measure for future consideration by the NQF. The Steering Committee did not identify any new information on which to reconsider its decision.

1428 Use of iron therapy when indicated

For More Information: Complete Measure Submision; Meeting/Call Proceedings

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 =18 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 3 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
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, MD 21244

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

If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up: The Steering Committee recommended the pediatric measure (#1433), which will be for time-limited endorsement, but not the adult measure. The Committee was asked to review its decision and rationale. The Committee agreed that its decisions should stand. Numerous problems with the adult measure were expressed, as noted under the Importance criterion. The pediatric measure was recommended for endorsement because it has a much better definition of when iron therapy is indicated; there is no clear evidence to support the application of pediatric definitions to adults (e.g., Hb <11 for pediatric). Although the pediatric measure raised some issues under the Importance criterion, e.g., no data on performance gap, lack of evidence for the Hb<11 value, the Committee agreed with the pediatric experts' rationale that such a measure was needed to support the proactive management of iron deficiency anemia in pediatric patients in whom iron and ESA requirements often are higher.
The Steering Committee did not suggest changes to the adult measure. The Committee will review any new information received during the upcoming comment period to determine if the recommendation should be revisited.
Developer Follow-up:

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 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. All facility scores at 75th percentile indicated that ESRD patients are receiving iron therapy. The developer provided additional information that 3,700 out of 10,000 patients who met the denominator specifications were not receiving iron therapy. 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 ng/ml rather than <100 ng/ml. The exclusion of Hb ≥12 may be too high because 12 is the upper limit; perhaps Hb 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 the patient is slightly deficient in other values, then iron might not be clearly indicated. Even if Hb <10 and ferritin = 90, the patient may not be iron deficient. There is no evidence that ferritin and TSAT need simultaneous measurement. 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, but an intermediate outcome of hemoglobin levels is a better measure.

Public and Member Comment
One commenter expressed support of the Committee's decision and one comment was from the steward on its rationale that the measure is important because prudent use of IV iron improves management of anemia by lowering the dose of ESA needed and the cut-point of 100 ng/mL was chosen because this is a level below which there is clear consensus about iron deficiency for all dialysis patients receiving an ESA.
The Steering Committee did not identify any new information on which to reconsider its decision.

1429 Avoidance of iron therapy in iron overload
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 greater than =50% during the study period. Denominator Statement: All adult (greater than =18 years) hemodialysis (HD) and peritoneal dialysis (PD) patients in the facility for the entire three-month reporting period who had serum ferritin greater than =1200 ng/mL or TSAT greater than =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 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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
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 as 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; therefore, 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, and is therefore largely irrelevant in this measure (40% may be a better upper limit). Hence the measure is really focused on ferritin > 1,200 ng/ml. The developer provided additional information from CROWNweb sample: 10,000 out of 40,000 patients who met the denominator criteria 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.
Public and Member Comment Two commenters asked for this measure to be reconsidered and one comment was from the measure steward on its rationale that the measure is intended to minimize harm. The Steering Committee did not identify any new information on which to reconsider its decision.

1432 Dietary sodium reduction advice
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
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. The measure reports the provider's perspective and is susceptible to becoming a documentation/checkbox measure, or to being fulfilled by just giving patients an information sheet. There is a critical need for measures that address patient self-management from the patient perspective, e.g., whether the patient reports receiving counseling or what is learned; however, this measure won't do that. Some Committee members noted that patients may not be aware of the link between sodium intake and volume, but despite its flaws, the measure will raise awareness of the need to address dietary sodium.
Public and Member Comment One commenter encouraged reconsideration plus the inclusion of other dietary advice; one comment was from the measure steward on its rationale for why dietary sodium restriction is fundamental to the management of hypertension and volume control. The Steering Committee did not identify any new information on which to reconsider its decision.

1434 Sodium profiling practice for hemodialysis
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
1. Importance to Measure and Report: Y-4: N-16 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Data on prevalence of sodium profiling or performance gap were not presented. Evidence regarding the use and consequences of the practice was weak. There was no discussion of when sodium profiling might be appropriate (e.g., for 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 being a performance measure.
Public and Member Comment One comment was from the measure steward on its rationale based on the potential deleterious effects of sodium profiling. The Steering Committee did not identify any new information on which to reconsider its decision.

1435 Restriction of dialysate sodium
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
1. Importance to Measure and Report: Y-2; N-18 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Data concerning the frequency of dialysate sodium >138 were not available, and no sub-group analysis of dialysate sodium use has been done. The measure is based on a reasonable hypothesis, but not strong evidence. Evidence to support the specific threshold of 138 was not provided.
Public and Member Comment One comment was from the measure steward on its rationale for how this measure has the potential to lower the net sodium gain by dialysis patients during dialysis treatments. The Steering Committee did not identify any new information on which to reconsider its decision.

1437 Utilization of dialysis duration of four hours or longer for patients new to dialysis
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
1. Importance to Measure and Report: Y-6; N-14 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Although it is clear that several outcomes are better when "more" dialysis is compared with "less" treatment, and that there is wide variation in dialysis prescription across dialysis facilities; the specific link to longer dialysis sessions when prescribed for 3x/week has less support. More frequent hemodialysis treatments (> 3x/week) improve solute clearance (e.g., urea measured by Kt/Vurea) and removal of volume; however, there is little convincing evidence that a cut-off of 4 hours of treatment when delivered 3x/week 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/week for 6-8 hours); 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 hours. The DOPPS is an observational study, and there were correlations in addition to 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 hours, 3x/week). KDOQI will have released a clinical practice guideline by the end of this year, and KDIGO probably 18 months after then. Some Committee members thought that even with the limitations on evidence, the 4-hour timeframe was sufficiently established to warrant a performance measure and that 4 hours should be considered a minimum standard. However, a Committee member asked why this measure would be applicable to new but not all patients.
Public and Member Comment No comments received on this measure.

1439 Utilization of high ultrafiltration rate for fluid removal
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
1. Importance to Measure and Report: Y-4; N-14 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Data on prevalence or performance gap were not presented. Although some published data show 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, has not been assessed. The quoted guideline focuses on intermediate outcomes of euvolemia and normotensive, not the specific ultrafiltration rate.
Public and Member Comment One commenter stated that a pre-defined metric may be important in further understanding the relationship between fluid overload and patient outcomes. The Steering Committee did not identify any new information on which to reconsider its decision.

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

For More Information: Complete Measure Submision; Meeting/Call Proceedings

Description: Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.
Numerator Statement: Number of patients with 3-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
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, MA 02142

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

If applicable, Conditions/Questions for Developer:
Developer Response:
Steering Committee Follow-up: The Steering Committee recommended the hypercalcemia measure (1454), considering it an indicator of toxicity of drug therapies. The hyperphosphatemia measure was not recommended, which raised the question why it was not also considered an indicator of toxicity.
The Steering Committee noted that the primary rationale for the different decisions was a difference in the causes and treatment responses. Hypercalcemia is related to drug therapies including calcium, Vitamin D, calcium-based binders; and the response to high levels is to decrease or remove therapies. Hyperphosphatemia in contrast reflects the kidney disease state, and there is also the possibility that high serum phosphorus results from metabolic bone disease with high turnover, for instance from high parathyroid hormone activity. Hyperphosphatemia may be treated with dietary restriction, longer or more frequent dialysis, or additional therapy with phosphate binders, which is a controversial aspect of care. Although care for individual patients should address hyperphosphatemia, the current evidence did not warrant a specific threshold performance measure.
Developer Follow-up:

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 of lowering phosphorus on morbidity and mortality is not known. Use of calcium-based vs. non-calcium-based binders is a very controversial area. 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 measures. 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 > 6.0 vs. 3.5-5.0 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.

Public and Member Comment
Five commenters (including the measure developer) urged reconsideration of the measure; one commenter urged the Committee to not reconsider its decision. The rationale given for reconsideration included association with mortality, importance as a biomarker for monitoring, importance of managing mineral metabolism, and concern about the effect of bundled payment on quality. The Steering Committee again discussed this measure after the comment period and while they did acknowledge that regulating bone and mineral metabolism is vital to care of dialysis patients, the evidence for the recommended 6mg/dl cutoff was not strong enough to support a performance measure. It also noted that there is a current performance measure (NQF# 0255-Measurement of Serum Phosphorus Concentration) that addresses monitoring serum phosphorus in dialysis patients. The Committee did not change its decision on this measure.

1461 Proportion of patients with hypophosphatemia
For More Information: Complete Measure Submision; Meeting/Call Proceedings
Description: Proportion of patients with 3-month rolling average of serum phosphorus less than 2.5 mg/dL. Numerator Statement: Number of patients in the denominator with 3-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 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, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
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's not clear that feeding them will help.
Public and Member Comment Three commenters (including the measure steward) encouraged reconsideration of this measure. The rationales included CMS will use the measure whether endorsed or not, association with mortality, and the steward's rationale emphasizing the importance of serum phosphorus as a marker of poor health and/or inadequate therapeutic decisions. The Steering Committee did not identify any new information on which to reconsider its decision.

1464 Standardized hospitalization ratio for days
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 The denominator of the SHR uses expected hospital days calculated from a Cox model (Cox, 1972) as extended to handle repeated events (Lawless and Nadeau,1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). For computational purposes, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and computational methodology as developed in Liu, Schaubel and Kalbfleisch (2010). A stage 1 model is first fitted to the national data with piecewise-constant baseline rates stratified by facility; hospitalization rates are adjusted for patient age, race, sex, diabetes, ethnicity, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline hospitalization rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The linear predictor for each patient based on the regression coefficients in the stage 1 model is then used to compute a risk adjustment factor that is used as an offset in the stage 2 model. N/A Level of Analysis: Facility/Agency Type of Measure: Outcome Data Source: Electronic administrative data/claims; Public health data/vital statistics Data for the hospitalization measures are derived from an extensive national ESRD patient database, which is largely derived from the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. Information on hospitalizations is obtained from Medicare Inpatient Claims Standard Analysis Files (SAFs). Measure Steward: Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: No Rationale: Did not pass Importance to Measure and Report
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 believed that how long a patient stays in the hospital is not only an indicator of patient condition when admitted, but also of hospital practices and quality. Therefore, this measure should not be a performance measure.
Public and Member Comment The measure steward commented on its rationale that SHR Days is significantly correlated with important facility practices and outcomes and was meant to be measured along with SHR Admissions as a concise summary of a facilities' experience with hospitalizations. The Steering Committee considered the developer's rationale but did not change its decision because the length of stay in a hospital is also affected by hospital practices, not just the patient's condition on admission.

1477 National Healthcare Safety Network (NHSN) intravenous (IV) antibiotic start measure

For More Information: Complete Measure Submision; Meeting/Call Proceedings

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. Rates are stratified by single greatest risk factor for infection—type of vascular access. The vascular access variables that are included in this analysis are arteriovenous (AV) fistula, AV graft, permanent central line, temporary central line. If more than one access type is present the antibiotic start is attributed to the access with the greatest risk (i.e., arteriovenous (AV) fistulaless than AV graftless thanpermanent central lineless thantemporary central line). Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters)
Details of stratified measures:
1. IV antibiotic start rate in CVC (central venous catheter) patients = the numerator below divided by denominator below times 100
1a. NUMERATOR. Events are included in the numerator if the "In-unit IV antimicrobial start" field on Form 57.109 is checked AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and "Port access device".
2. IV antibiotic start rate in AVG (arteriovenous graft) patients = the numerator below divided by denominator below times 100
2a. NUMERATOR. Events are included in the numerator if the "In-unit IV antimicrobial start" field on Form 57.109 is checked AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119.
3. IV antibiotic start rate in AVF (arteriovenous fistula) patients = the numerator below divided by denominator below times 100
3a. NUMERATOR. Events are included in the numerator if the "In-unit IV antimicrobial start" field on Form 57.109 is checked AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device".
3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119.
Level of Analysis: Facility/Agency; Population: national
Type of Measure: Other. This measure is both process and outcome
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, GA 30333

Steering Committee Recommendation for Endorsement: Y-2; N-18
Rationale: Although an important topic for measurement, the validity, usability, and feasibility were concerns.

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-0
(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 2 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 2 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 reliability testing was reported, but data element validity 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-0
(3a. Meaningful/useful for public reporting and quality improvement; 3b. Harmonized; 3c. Distinctive or additive value to existing

1477 National Healthcare Safety Network (NHSN) intravenous (IV) antibiotic start measure
measures) Rationale: There was some confusion that the measure was intended to identify inappropriate antibiotic starts rather than to serve as a proxy for infection.
4. Feasibility: C-0; P-9; M-11; 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: 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.
Public and Member Comment One commenter suggested a measure of antibiotic use was appropriate; however, this measure is specified to use antibiotic use as a proxy for infection not for appropriate use of antibiotics. A measure of blood stream infections (1460) was recommended.

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

For More Information: Complete Measure Submision; Meeting/Call Proceedings

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 2 working days of the month.
Exclusions: Patients receiving inpatient hemodialysis are excluded
Adjustment/Stratification: other Simple stratification Both the numerator and denominator are stratified by vascular access type since vascular access type is the single greatest risk factor for access-related bloodstream infection in this population. The vascular access variables that are collected and included in this analysis are: arteriovenous (AV) fistula, AV graft, permanent central line, and temporary central line. If more than one access type is present in a patient, the bloodstream infection event is attributed to the access type with the greatest risk (i.e., AV fistula less than AV graft less than permanent central line less than temporary central line). During denominator collection (see URL below), the user is asked to count each patient as having only 1 vascular access type, following the algorithm described. During numerator collection, all vascular access types present at the time of the bloodstream infection event are reported and the algorithm is applied during analysis of the data. Both the numerator and denominator are stratified by patient vascular access type, where permanent central lines are defined as tunneled central lines (or tunneled central venous catheters) and temporary central lines are defined as nontunneled central lines (or nontunneled central venous catheters).
Details of stratified measures:
1. Access-related BSI rate in CVC (central venous catheter) patients = the numerator below divided by denominator below times 100
1a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked, along with either "Vascular access" or "Uncertain" (under 'Suspected source of positive blood culture'), AND any of the following fields on Form 57.109 under 'Vascular accesses' are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
1b. DENOMINATOR. The denominator equals the sum of the numeric values entered for the following fields on Form 57.119: "Permanent central line", "Temporary central line", and ""Port access device".
2. Access-related BSI rate in AVG (arteriovenous graft) patients = the numerator below divided by denominator below times 100
2a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked, along with either "Vascular access" or "Uncertain" (under 'Suspected source of positive blood culture'), AND if the field labeled "Graft" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Permanent central line", "Temporary central line", or "Port access device".
2b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Graft" on Form 57.119.
3. Access-related BSI rate in AVF (arteriovenous fistula) patients = the numerator below divided by denominator below times 100
3a. NUMERATOR. Events are included in the numerator if the "patient with positive blood culture" field on Form 57.109 is checked, along with either "Vascular access" or "Uncertain" (under 'Suspected source of positive blood culture'), AND if the field labeled "Fistula" on Form 57.109 under 'Vascular accesses' is checked as being present AND none of the following fields on the same form are checked as being present: "Graft", "Permanent central line", "Temporary central line", or "Port access device".
3b. DENOMINATOR. The denominator equals the numeric value entered for the field labeled, "Fistula" on Form 57.119.
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, GA 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.

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 in performance. The rationale for considering this criterion as not met was the lack of evidence for identifying the cause of a bloodstream infection, especially given that measure 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-0
(2a. Precise specifications; 2b. Reliability testing; 2c. Validity testing; 2d. Exclusions justified; 2e. Risk adjustment/stratification; 2f. Meaningful differences; 2g. Comparability; 2h. Disparities)

1478 National Healthcare Safety Network (NHSN) vascular access-related bloodstream infection measure
Rationale: A primary issue was lack of specificity for determining that the infection was related to vascular access. Each facility can decide how and who makes that determination. CDC only provides list of common skin contaminants for consideration. A question was raised as to whether this measure will miss incident dialysis patients coming from the hospital who have the highest risk of catheters for access, infections, and readmission to the hospital. Patients who are transiting at another clinic and those who are no-shows or who are hospitalized on one of those 2 days of the month would be excluded and their infections missed. The developer clarified that the denominator statement of patients on first 2 days of 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 for which the 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 a 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: This measure is usable only if it can be accurately determined that the infection is attributable to vascular access; therefore, 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 dialysis 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.
Public and Member Comment No comments received on this measure.

1456 Bacteremia (rate)
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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, MD 21244
Steering Committee Recommendation for Endorsement: Final: No; Initial: Y-9; N-11 Rationale: This measure more directly competes with the CDC measure 1460; therefore, both this measure and measure 1457 were reviewed as competing measures. Because this measure was untested it could not be demonstrated to be superior to a tested measure with adequate reliability and validity; therefore, it was not recommended for endorsement.
If applicable, Conditions/Questions for Developer: Do you have any testing data on reliability and validity? Can you clarify why you indicated the measure as a process measure if it's 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? Developer Response: 1. Do you have any testing data on reliability and validity? The validity and reliability of collecting the data elements used in both the CMS and CDC proposed infection measures from clinical data at US dialysis facilities has been demonstrated during the last several years through the voluntary CDC National Health Safety Network (NHSN) surveillance program for access-related infections. In addition, there have been numerous studies of vascular access-related infection rates among dialysis patients which have reported similarly defined infection outcomes as indicated in the forms submitted to NQF regarding these measures. The reviews of the scientific literature made by practice guideline committees (KDOQI, CDC, UK Renal Assoc, Australian Council on Healthcare Standards) provide ample evidence that the data elements used in calculation of the proposed infection measures are reliable and valid data elements. CMS is delighted that the NQF Steering Committee has identified infection rates as an important outcome for dialysis patients and CMS expects to implement data collection and measurement for the final definitions approved by the NQF. Multiple definitions for both the numerator and denominator of an infection measure have been proposed by both the CDC and CMS, with different goals and practical issues motivating each definition. The CMS measures 1456 and 1457 differ from the CDC measure 1460 in a few ways. 1) The CMS measures count only those infections in which IV antibiotics were administered and in which the blood culture results were consistent with bacteremia as indicated by the caregiver. The CDC measure appears to count all positive blood cultures, as noted in their measure description. 2) The CMS definition that limits infection ascertainment to those patients with IV antibiotic use was intended to reduce data collection burden by limiting the review of laboratory blood test results to the small number (2-5%) of patients with IV antibiotics. Clinical technical expert panel members felt that this restriction would focus the measure upon patients with serious infections while at the same time greatly reducing data collection burden. The CMS proposal to limit the infection definition to only those positive blood cultures consistent with a diagnosis of bacteremia was intended to reduce the false positive rate of the measure. Furthermore, this determination of access-related bacteremia is already required of dialysis units as part of claims reporting for the V8 modifier. 3) The CDC definition is less subjective, but does not spell out how to deal with multiple blood cultures, one of which was positive, but with multiple negative results, for example. 4) While CMS believes that the conditions of positive blood culture and IV antibiotic use are both important, for the reasons given above, CMS is prepared to measure and test infection rates according to any or all of the specifications for the numerator provided in these three proposed measures. 5) Both CMS and the CDC have recommended that, in addition to data needed to calculate an overall infection rate, data also be collected concerning attribution to vascular access. This would allow calculation of access type-specific infection rates, which would be valuable to a facility in their attempts to identify the causes for elevated infection rates. 6) The CMS and CDC measures differ with regard to the denominator specification of time at risk. CMS believes that both the CDC and the CMS proposals are valid and implementable. The CMS definition, which accounts for partial months at risk by removing patient-months at the time of death or transplant or transfer is more precise, but would have relatively modest impact upon the calculated rate. CMS plans to implement collection of the relevant data elements in calendar year 2011 and, upon approval by the NQF, will test the

validity and reliability of the resulting data flow as described in detail below. In addition to evaluation of the approved measure, CMS will evaluate measures based on the alternative definitions suggested above and will provide data demonstrating the reliability and validity of using those alternative definitions in the calculation of infection rate measures.

Our proposed testing plan embodies 3 important features as described below: (a) assessment of reliability in collecting these particular data from US dialysis units, (b) validity assessment, and (c) proposed data collection that minimizes data collection burden.

(a) Reliability assessment of access-related bacteremia data to be collected for proposed measure

(i) It is important to note that, previously, the CDC's National Health Safety Network (NHSN) project has demonstrated that access-related bacteremia data can be reliably collected from nearly 150 volunteer hemodialysis (HD) units. However, it is our understanding to be confirmed with the CDC that the geographic distribution of these voluntary sites is not nationally representative. Nonetheless, the results from this NHSN project can serve as an important set of statistics that can be used for comparative purposes regarding distribution of rates of access-related bacteremia among HD patients. However, since the CDC program is based on volunteer participation, is limited in its geographic representation (< 3% of dialysis facilities currently participate, with geographic distribution not representative of US), and substantial training with follow-up/feedback is a key feature of study participation, it is not known to what extent the NHSN findings will be representative of access-related bacteremia rates across the US.

(ii) In July, 2010, CMS required all US dialysis facilities to report, each month, all cases of dialysis access-related bacteremia in hemodialysis patients (HCPCS Modifier V8):

Figure 1: Definition of Medicare Claims HCPCS Modifier V8

'Dialysis access-related infection present (documented and treated) during the billing month. Reportable dialysis access-related infection is limited to peritonitis for peritoneal dialysis patients or bacteremia for hemodialysis patients. Facilities must report any peritonitis related to a peritoneal dialysis catheter, and any bacteremia related to hemodialysis access (including arteriovenous fistula, arteriovenous graft, or vascular catheter) if identified during the billing month. For individuals that receive different modalities of dialysis during the billing month and an infection is identified, the V8 code should only be indicated on the claim for the patient's primary dialysis modality at the time the infection was first suspected. Non-access related infections should not be coded as V8. If no dialysis-access related infection is present by this definition, providers should instead report modifier V9.'

The HCPCS Modifier V8 claims data and related modifiers have now been collected since July, 2010 with the first of these data expected to be available for analysis by March, 2011. These claims data will serve as another important set of statistics to be used for comparative purposes regarding distribution of rates of access-related bacteremia among HD patients, nationally and at a facility-level. These data will be nationally representative since they are provided by all dialysis units in the US. Furthermore, based on claims data reporting, rates of overall bacteremia will be determined to assess the percentage of reported cases of bacteremia in HD patients which are access-related, and to describe this on an overall national-level as well as the distribution of this percentage across US HD facilities (i.e., facility-level distribution).

(iii) When a facility does not report a HCPCS Modifier V8 for a particular patient during a month, it is not known the extent to which this is due to a patient not having a bacteremia versus the information not being available in a patient's medical records. The data collection we have proposed using CROWNWeb will allow quantification of unavailable information in having dialysis units provide the following information for patients who have been given a new IV antibiotic prescription during the month, and specifically asking whether the information was unavailable for whether blood cultures were consistent with bacteremia:

Proposed Data Collection Elements for Access-related Bacteremia Measure

(1) Did this patient initiate a new intravenous (IV) antibiotic therapy this month? (either newly prescribed in the unit this month, or patient discharged from the hospital/other health care facility with a new antibiotic prescription this month)

Yes No

(2) Were the blood cultures consistent with bacteremia?

Yes No Unavailable Blood cultures not collected

If YES, please answer remaining question:

(3) Was this bacteremia related to the dialysis access?

No, this was a non-access related infection
Yes HD- Catheter
Yes HD-Arteriovenous FISTULA
Yes HD-Arteriovenous GRAFT
Yes PD- Catheter (Use of this choice to be evaluated later by PD C-TEP)
Unavailable

Statistical analyses will be performed to assess inter-rater agreement between variables collected via claims data V8 and V9 modifier data and those collected via CROWNWEB for our proposed time-limited access-related bacteremia measure. Measures of inter-rater agreement will include the percent of identical values between the two raters, the unweighted kappa coefficient for nominal variables or weighted kappa for ordinal variables, and the intraclass correlation coefficient for continuous variables. For dichotomous variables, we will use McNemar's test to test whether the claims data and CROWNWEB data are likely to report a given response. These analyses will be performed separately for each variable used to calculate the measure. We will also calculate a summary variable, such as the percent discrepant among variables checked, for each patient and each facility.

1456 Bacteremia (rate)

We will consider discrepancies in two ways: First, we will calculate summaries of discrepancies for each variable across all facilities. This calculation will alert us to any variables that appear to be difficult with regards to reliable data collection. Second, we will calculate summaries of discrepancies over all variables for each facility. The distribution of these discrepancy summaries will be assessed for its variability and possible outliers. This analysis will alert us to any facility-specific issues related to data reliability. An effort will be made to contact some of these facilities with highly discrepant results to understand the reasons for this. In addition, we plan to also contact some of the facilities with a high % of unavailable information (regarding blood cultures results) in order to understand the reasons for the high % of unavailable information.

Although the major focus of reliability testing will be the assessment of concordance/discordance between the data collected via CROWNWeb versus Claims data, the distribution of access-related bacteremia rates across facilities represented in CROWNWeb, Claims data, and the CDC NHSN program will also be described.

(b) Validity assessment of access-related bacteremia data to be collected for proposed measure

As indicated previously, prior guidelines (KDOQI, CDC, UK Renal Association, Australian Council on Healthcare Standards) have indicated the importance of limiting rates of access-related bacteremia in hemodialysis patients based on: (1) evidence from numerous randomized clinical trials and other studies demonstrating the ability to reduce catheter-related bacteremia by various approaches, and (2) higher rates of bacteremia are strongly associated with higher rates of serious infection (e.g. septicemia) which are known and have shown to be closely related to higher rates of death and hospitalization, and higher costs. These prior studies provide ample evidence of the face validity of the proposed measure.

Prior results based on 32 facilities participating in the CDC NHSN program have provided preliminary evidence indicating wide variability in access-related bacteremia rates across these 32 facilities (Klevens et al., Seminars in Dialysis, 2006). Furthermore, we recently have published preliminary findings demonstrating high variability in access-related infection rates across all US dialysis units based on CMS Claims data (Lueth et al., JASN, volume 21, 2010, page 468A). However, as part of our time-limited testing of the proposed measure, we will describe the variation in access-related bacteremia rates across all US dialysis units as part of the assessment of construct validity. Correlation between facility access-related bacteremia rates and facility SMR and facility SHR will also be performed. Furthermore, access-related bacteremia rates will be described separately for each access type to determine the consistency with numerous prior studies which have shown much higher rates of infection and/or bacteremia to be associated with catheters versus arteriovenous fistulae or grafts. The above proposed analyses will form the basis of determining the construct validity of the proposed measure.

(c) The required data collection is not overly burdensome to dialysis units

Limiting data collection burden is an important consideration in developing a new measure as indicated by NQF members, as well as by CMS Data-TEP and CMS Clinical TEP members. To greatly decrease data collection burden, reporting of access-related bacteremia for the CMS proposed measure is limited to patients having been given a new IV antibiotic prescription during the reporting month. The CMS Clinical Technical Expert Panel felt that this restriction would provide a focus upon serious infections while limiting data collection burden. This was embraced by the Data Technical Expert Panel which consisted of representatives from all types of US dialysis organizations (e.g., LDOs, MDOs, SDOs, not-for-profit dialysis organizations, etc). Since only 2-5% of HD patients on average receive a new IV antibiotic prescription during a month, the CMS measure is expected to require data collection for ~5 patients per month on average in a facility treating 100 HD patients. Thus, no data collection will be required for 95% of patients in a typical facility for access-related bacteremia. Dialysis organization representatives indicated that whether a patient received a new IV antibiotic prescription is typically available in the patient's medical records.

2. Can you clarify why you indicated the measure as a process measure if it's being used as a marker for infection? Did you intend to develop process measures about diagnosing and treating infections?

To fit with the NQF's definition of a process measure, please view our access-related bacteremia measure as an outcome measure and we can make this change on the measures form for the future. We had proposed two measures which would have served as process measures regarding diagnosis and follow-up of infections (e.g. percentage of patients with an IV antibiotic prescription for whom blood culture results were unavailable or cultures not collected, and (2) percentage of patients with an IV antibiotic prescription for whom whether clinical confirmation of the suspected infection was unavailable (i.e. suggesting that follow-up may not be well-documented). However these were not approved by the NQF.

3. Can you clarify or provide reference to regulatory requirements for ESRD facilities to provide data to CROWNweb?

The CMS Conditions for Coverage contain the regulatory requirements that facilities have to submit data to CW beginning last year Feb 1, 2009. This is stated in sec 494.180(h) of the final rule for the updated CfCs passed in 2008 and published in the Federal Register. Facilities are being phased in for reporting, however the regulations as written make submission mandatory, which will be for all facilities upon national roll-out. Additionally, the required data elements for the measures are already included in the current CW business requirements.

See June 2008 Conditions for Coverage at http://projectcrownweb.org/assets/massmailings/june2008.pdf."

Steering Committee Follow-up: An untested measure without reliability and validity data could not be demonstrated to be superior to a tested measure with adequate reliability and validity data. NQF and the ESRD Steering Committee requested that CMS and CDC collaborate on submitting one measure of bacteremia in ESRD patients, stratified by type of vascular access, that will meet both government agencies' needs and for which data could eventually be exchanged electronically between the two agencies. For now, at a

1456 Bacteremia (rate)
minimum, facilities should be able to submit the same data to both agencies. Developer Follow-up: CMS and CDC agreed to work together on one measure; however, they were not able to accomplish identifying cross-walked specifications for use with CROWNweb in the time allowed for this project. CMS agreed that it could use the CDC definitions as long as the NHSN form or data system is not required because ESRD facilities are required to submit data through CROWNweb. NQF clarified that although detailed measure specifications often identify specific data collection tools (e.g., CMS' MDS for nursing home measures), endorsed measures can be implemented with different data collection tools and systems as long as the data definitions in the endorsed measure and measure construction logic are followed. The CDC also agreed that the measure does not require use of the NHSN data tools and systems and agreed to clarify definitions if needed. If #1460 is endorsed, CMS will implement the measure specifications into its CROWNweb system by a date yet to be determined. CMS and CDC agreed to pursue data sharing arrangements so that ESRD facilities could submit data to either agency. Both CROWNweb and NHSN have capacity for batch submission of data.
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. Although a large variation across dialysis facilities was asserted on the submission form, 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-0 *(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. Therefore, it is a measure of bacteremia not of a process. 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 are mandated in CROWNweb. The numerator requirement for including 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.
Public and Member Comment One commenter Suggested a measure of access-related blood stream infection was needed. The Steering Committee recommended 1460, which is stratified by type of vascular access.

1457 Access-related bacteremia (rate)
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Final: No; Initial: Y-11; N-9 pending comparison of competing measures Rationale: This measure and measure 1456, which more directly competes with the CDC measure 1460, were reviewed as competing measures. Because this measure is untested it could not be demonstrated to be superior to a tested measure with adequate reliability and validity; therefore, it was not recommended for endorsement.
If applicable, Conditions/Questions for Developer: Do you have any testing data on reliability and validity? Can you clarify why you indicated this measure as a process measure if it's 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? Developer Response: See developer response to measure 1456. Steering Committee Follow-up: An untested measure without reliability and validity data could not be demonstrated to be superior to a tested measure with adequate reliability and validity data. NQF and the ESRD Steering Committee requested that CMS and CDC collaborate on submitting one measure of bacteremia in ESRD patients, stratified by type of vascular access, that will meet both government agencies' needs and for which data could eventually be exchanged electronically between the two agencies. For now, at a minimum, facilities should be able to submit the same data to both agencies. Developer Follow-up: CMS and CDC agreed to work together on one measure; however, they were not able to accomplish identifying cross-walked specifications for use with CROWNweb in the time allowed for this project. CMS agreed that it could use the CDC definitions as long as the NHSN form or data system is not required because ESRD facilities are required to submit data through CROWNweb. NQF clarified that although detailed measure specifications often identify specific data collection tools (e.g., CMS' MDS for nursing home measures), endorsed measures can be implemented with different data collection tools and systems as long as the data definitions in the endorsed measure and measure construction logic are followed. The CDC also agreed that the measure does not require use of the NHSN data tools and systems and agreed to clarify definitions if needed. If #1460 is endorsed, CMS will implement the measure specifications into its CROWNweb system by a date yet to be determined. CMS and CDC agreed to pursue data sharing arrangements so that ESRD facilities could submit data to either agency. Both CROWNweb and NHSN have capacity for batch submission of data.
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 an important goal, and access-related infections 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

1457 Access-related bacteremia (rate)
determination that infection is related to vascular access. However, the denominator is all ESRD patients, so it is a measure of bacteremia not of a process. The measure requires a determination that the infection was related to vascular access, but it 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-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 are mandated in CROWNweb. The CMS representative said 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 the CDC measure.
Public and Member Comment One commenter Suggested a measure of access-related blood stream infection was needed. The Steering Committee recommended 1460, which is stratified by type of vascular access.

1455 Access-related bacteremia—using Medicare claims (rate)

For More Information: Complete Measure Submision; Meeting/Call Proceedings

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 & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244

Steering Committee Recommendation for Endorsement: Y-7; N-13
Rationale: The measure is not tested, and claims data is thought to be an inferior source of data compared to record abstraction.

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 this measure as a process measure, but it appears to be an outcome measure. Although a large variation across dialysis facilities was asserted on the submission form, 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. Another question was raised about the reliability and validity of claims 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 if the episode bridges 2 calendar months and the modifier is used in each of those months. The developer explained that the measure uses only Medicare claims because it had access to only 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 measure does not add another layer of reporting.

Public and Member Comment
No comments received on this measure.

1449 Unavailable blood culture results (percentage)
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Y-1; N-18 Rationale: The Committee did not think the measure was necessary or appropriate for public reporting.
1. Importance to Measure and Report: Y-9; N-9 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: Data on performance gaps were not provided. The measure would be considered to meet the criterion if it is viewed as a process measure of performing blood cultures. The rationale for considering this criterion as 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. The term "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 to detect "gaming of the system" or report on a process, this measure might have some usefulness. However, a measure of missing data is not particularly useful for pubic reporting or quality 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.
Public and Member Comment No comments received on this measure.

1453 Clinically confirmed infection (rate)
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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, MD 21244
Steering Committee Recommendation for Endorsement: Withdrawn Rationale: The developer withdrew the measure when measure 1469 was not recommended because all three clinical confirmation measures would be needed.
Public and Member Comment No comments received on this measure.

1469 Clinically confirmed access-related infection (rate)
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 an 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. 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, MD 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 if it was related to vascular access.
1. Importance to Measure and Report: Y-9; N-9 *(1a. Impact; 1b. Performance gap; 1c. Outcome or Evidence)* Rationale: The measure is listed as a process measure, but it is really an outcome measure. It was not constructed to reflect the process of clinically confirming an infection. The evidence did not address how to clinically confirm an infection or how to determine if 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 because the specifications do not define clinically confirmed or vascular access-related, the results may be inconsistent. There could be some problem with a 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.
Public and Member Comment No comments received on this measure.

1450 Unavailable clinical confirmation (percentage)
For More Information: Complete Measure Submision; Meeting/Call Proceedings
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 & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Steering Committee Recommendation for Endorsement: Withdrawn Rationale: The developer withdrew the measure when measure 1469 was not recommended because all three clinical confirmation measures would be needed.
Public and Member Comment No comments received on this measure.