NATIONAL QUALITY FORUM

TO: NQF Members and Public

FR: NQF Staff

RE: Voting draft report for *National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report*

DA: May 23, 2011

BACKGROUND

Measuring quality of care for end stage renal disease (ESRD) is of critical importance, because survival is dependent on dialysis treatments or renal transplant. The recommended measures are intended to supplement NQF-endorsed measures related to dialysis care to facilitate efforts to improve the quality of care delivered to ESRD patients, particularly pediatric patients. An upcoming endorsement maintenance project for renal disease will review NQF-endorsed® measures as well as new measures for any aspect of renal disease.

A 20-member Steering Committee representing a range of stakeholder perspectives was appointed to review a total of 32 candidate standards for quality performance in ESRD care. The Steering Committee recommended 11 measures for endorsement. The comment period for the draft report opened on March 24, 2011 and concluded on April 22, 2011

Comments and Revised Voting Report

NQF received 161 comments from 32 organizations and individual on measures both recommended and not recommended for endorsement as well as general comments on the Draft Report. The distribution of individual comments by Member Council follows:

- Consumers: 11 comments
- Health Professionals: 24 comments
- Purchasers: 28 comments
- Public Health/Community: 0 comments
- Health Plans: 5 comments
- Quality Measurement, Research, and Improvement: 17 comments
- Providers: 25 comments
- Supplier and Industry: 5 comments
- Non-members: 46 comments

A table of complete comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee, is posted to the ESRD project page under the Public and Member comment section.

The revised draft document, *National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report*, is posted on the ESRD project page on the NQF web site, along with the following additional information:

- measure submission forms; and
- meeting and call summaries from the Steering Committee's discussions.

Revisions to the draft report and the accompanying measure specifications are identified as redlined changes. (Note: Typographical errors and grammatical changes have not been red-lined to assist in reading.)

The Steering Committee reviewed all comments received and did not make any changes to its measure recommendations for NQF member voting. Just as in the Steering Committee's deliberations, the comments on similar measures were divided. The Committee concluded that the comments reflected in prior discussions and its recommendations for endorsement should be voted on by the NQF membership.

COMMENTS AND THEIR DISPOSITION

The Steering Committee reviewed the comments and focused their discussion on specific measures or topic areas with the most significant and reoccurring issues that arose from the comments. Comments about specific measure specifications and rationale also were forwarded to the developers, who were invited to respond.

Overall, the comments were positive and supportive of the recommended measures. Several themes emerged in the comments including:

- whether measures of assessment frequency or method meet the NQF criteria of Importance to Measure and Report;
- expansion of the target population for some of the measures to include home dialysis patients in more measures and CKD stage 3 and 4 patients in the anemia measures;
- questions about the hospitalization measure; and
- reconsideration of the measure for serum phosphorus >6.

Comments on Measures Recommended For Endorsement

Expand target population

Commenters suggested including home hemodialysis patients in several of the recommended measures. The Steering Committee reviewed the possible inclusion of home hemodialysis patients and agreed they should be included unless evidence requires exclusion. It asked the measure developer to address whether these patients should be included in each of the measures. The measure developer agreed to include home hemodialysis for the following measures and submitted revised specifications

- 1418 - Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients
- 1424 - Monthly Hemoglobin Measurement for Pediatric Patients
- 1430 - Lower Limit of Hemoglobin 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

The developer did not change the exclusion in the following measures, but noted that CROWNWeb will collect data on these patients to allow for future evaluation and reconsideration of this exclusion:

- 1421 - Method of Adequacy Measurement for Pediatric Hemodialysis Patients
- 1423 - Minimum spKt/V for Pediatric Hemodialysis Patients
- 1425 - Measurement of nPCR for Pediatric Hemodialysis Patients

Some commenters suggested including CKD stage 3 and 4 in the following anemia measures. The Steering Committee noted that these measures were not developed or submitted to include the CKD population and would require additional development/testing. The measure developer also confirmed that these measures were not developed for the CKD population. The measures will remain as is and will be recommended for endorsement:

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

Question on whether measures meet NQF criteria

Multiple comments were submitted over concern that the assessment measures (frequency or method) do not meet NQF criteria for *Importance to Measure and Report*, and therefore should not be recommended for endorsement. A representative comment is *"They do not provide information on whether these data are being used in a way that will improve dialysis treatment; these measures will only provide information on whether the dialysis center recorded a patient's spKt/V, nPCR, and hemoglobin values each month. While measuring these values frequently comprises important process steps in the care of ESRD patients, having measures only of the frequency and not the data themselves is setting the bar particularly low."*

The Steering Committee identified the same issues while evaluating the measure as noted in the draft report. The Committee upheld its recommendations for endorsement because pediatric ESRD care is a new area of performance measurement and there was data demonstrating less than optimal performance. This would be re-evaluated at the time of endorsement maintenance.

- 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

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 examine the methodology for the calculation of the expected hospitalization rate.

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 as described by the developer in the measure submission and supplemental materials. The measure is recommended for endorsement.

Comments on Measures Not Recommended For Endorsement

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

Multiple comments were submitted to reconsider endorsement for this measure on the basis that the evidence is just as strong as for the hypercalcemia measure and that this measure may eventually be required because of the future bundled payment program. The Steering Committee discussed this measure at length and reiterated its original conclusion that the evidence was not sufficient to identify a specific threshold value and agreed that this measure did not pass the NQF criteria for *Importance to Measure and Report*.

In addition, the Committee noted that it agrees that phosphorus should be monitored and managed and there is currently an NQF-endorsed® measure that addresses monitoring of serum phosphorus in dialysis patients (NQF# 0255-Measurement of Serum Phosphorus Concentration).The initiation of a bundled payment system is not justification in itself for endorsement. Therefore, the Steering Committee did not change its decision and the measure is not recommended for endorsement.

NQF MEMBER VOTING

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on Tuesday, June 21, 2011, at 6:00 pm ET—no exceptions.

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR END STAGE RENAL DISEASE (ESRD) 2010: A CONSENSUS REPORT

DRAFT REPORT FOR VOTING

May 23, 2011

(5/24/11 clarification to #1460)

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR END STAGE RENAL DISEASE (ESRD) 2010: A CONSENSUS REPORT

TABLE OF CONTENTS

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR END STAGE RENAL DISEASE (ESRD) 2010: A CONSENSUS REPORT

EXECUTIVE SUMMARY

Measuring the quality of care for end stage renal disease (ESRD) is critically important, because patient survival depends on dialysis treatments or renal transplant. Currently in the United States, more than half a million people have received a diagnosis of ESRD and more than 360,000 are on dialysis treatment. Adjusted all-cause mortality rates for ESRD are roughly 6-8 times higher for dialysis patients than for the general population.[1] The measures recommended for endorsement as part of this project, along with previously endorsed measures, will help to facilitate quality of care of patients on renal dialysis, including pediatric patients.

This report presents the results of the evaluation of 32 measures considered under the National Quality Forum's Consensus Development Process (CDP). Eleven measures are recommended for endorsement as voluntary consensus standards suitable for public reporting and quality improvement.

- Frequency of adequacy measurement for pediatric hemodialysis patients (CMS)
- Method of adequacy measurement for pediatric hemodialysis patients (CMS)
- Minimum spKt/V for pediatric hemodialysis patients (CMS)
- Measurement of nPCR for pediatric hemodialysis patients (Time-limited) (CMS)
- Use of iron therapy for pediatric patients (Time-limited) (CMS)
- Monthly hemoglobin measurement for pediatric patients (CMS)
- Lower limit of hemoglobin for pediatric patients (CMS)
- Periodic assessment of post-dialysis weight by nephrologists (Time-limited) (CMS)
- Proportion of patients with hypercalcemia (CMS)
- Standardized hospitalization ratio for admissions (CMS)
- National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC)

NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR END STAGE RENAL DISEASE (ESRD) 2010: A CONSENSUS REPORT

BACKGROUND

Currently in the United States, more than half a million people have received a diagnosis of end stage renal disease (ESRD), a serious condition that is almost always fatal unless treated with dialysis or transplantation. More than 360,000 patients are on dialysis, nearly 1,200 of which are pediatric patients. ESRD is the only disease-specific condition that is explicitly guaranteed Medicare coverage. In 2008 costs for ESRD rose 13.2 percent from the previous year to equal $26.8 billion, or 5.9 percent of the total Medicare budget. Adjusted all-cause mortality rates for ESRD are roughly 6-8 times higher for dialysis patients than for the general population. ~~After a 2.1 percent decline in 2007, the adjusted incident rate of ESRD fell 1.1 percent to equal 350.8 per million population (more than 527,000 cases) in 2008.~~[1] Racial and ethnic differences continue to persist, with 2008 rates for African Americans and Native Americans 3.6 and 1.8 times higher, respectively, than the rate for Caucasians, and the rate for Hispanics 1.5 times higher than that for non-Hispanics.[2]

The recommended measures are intended to supplement National Quality Forum (NQF)-endorsed® measures related to dialysis care to facilitate efforts to improve the quality of care delivered to ESRD patients, particularly pediatric patients. An upcoming endorsement maintenance project for renal disease will review NQF-endorsed ESRD measures as well as new measures for any aspect of renal disease.

STRATEGIC DIRECTIONS FOR NQF

NQF's mission includes three parts: 1) setting national priorities and goals for performance improvement, 2) endorsing national consensus standards for measuring and publicly reporting on performance, and 3) promoting the attainment of national goals through education and outreach programs. As greater numbers of quality measures are developed and brought to NQF for consideration of endorsement, NQF must assist stakeholders in measuring "what makes a

difference" and addressing what is important to achieve the best outcomes for patients and populations.

Several strategic issues have been identified to guide consideration of candidate consensus standards:

DRIVE TOWARD HIGH PERFORMANCE. Over time, the bar of performance expectations should be raised to encourage achievement of higher levels of system performance.

EMPHASIZE COMPOSITES. Composite measures provide much-needed summary information pertaining to multiple dimensions of performance and are more comprehensible to patients and consumers.

MOVE TOWARD OUTCOME MEASUREMENT. Outcome measures provide information of keen interest to consumers and purchasers, and when coupled with healthcare process measures, they provide useful and actionable information to providers. Outcome measures also focus attention on much-needed system-level improvements because achieving the best patient outcomes often requires carefully designed care process, teamwork, and coordinated action on the part of many providers.

CONSIDER DISPARITIES IN ALL WE DO. Some of the greatest performance gaps relate to care of minority populations. Particular attention should be focused on identifying disparities-sensitive performance measures and on identifying the most relevant race/ethnicity/language/socioeconomic strata for reporting purposes.

NATIONAL PRIORITIES PARTNERSHIP

NQF seeks to endorse measures that address the National Priorities and Goals of the NQF-convened National Priorities Partnership (Partnership). The Partnership represents those who receive, pay for, provide, and evaluate healthcare. The National Priorities and Goals focus on these areas:

- patient and family engagement,
- safety,

- care coordination,
- palliative and end-of-life care,
- equitable access,
- elimination of overuse,
- population health, and
- infrastructure supports.

Some of the recommended measures address the following specific National Priorities:

- Improve the safety and reliability of America's healthcare system:
    - All healthcare organizations and their staff will strive to ensure a culture of safety while driving to lower the incidence of healthcare-induced harm, disability, or death toward zero. They will focus relentlessly on continually reducing and seeking to eliminate all healthcare-associated infections (HAIs) and serious adverse events.
- Eliminate overuse while ensuring the delivery of appropriate care:
    - All healthcare organizations will continually strive to improve the delivery of appropriate patient care, and substantially and measurably reduce extraneous service(s) and/or treatment(s), such as preventable emergency department visits and hospitalizations.

RELATED NQF WORK

In 2008, NQF endorsed 25 measures for ESRD care in the areas of anemia, dialysis adequacy, mineral metabolism, vascular access, influenza immunization, mortality, patient education, perception of care, and quality of life. See the report, National Voluntary Consensus Standards for End Stage Renal Disease Care: A Consensus Report.[3]

NQF'S CONSENSUS DEVELOPMENT PROCESS

NQF's National Voluntary Consensus Standards for ESRD project seeks to endorse additional ESRD measures for quality improvement and public reporting.

Evaluating Potential Consensus Standards

Candidate consensus standards were solicited through a Call for Measures on September 1, 2010. Thirty-two measures were evaluated for suitability as voluntary consensus standards for accountability and public reporting. The measures were evaluated using NQF's standard evaluation criteria.[4] Steering Committee subgroups rated each candidate consensus standard according to the subcriteria and identified strengths and weaknesses to assist the project Steering Committee in making recommendations. The 20-member, multistakeholder Steering Committee provided final evaluations of the four main criteria—importance to measure and report, scientific acceptability of the measure properties, usability, and feasibility—and made endorsement recommendations. Measure developers were available during Committee discussions to respond to questions and clarify any issues or concerns.

Overarching Measure Evaluation Issues

The Steering Committee encountered several overarching issues during its discussions and evaluations of the measures. These issues were factored into the Committee's ratings and recommendations for multiple measures and are explained below rather than with each individual measure in the evaluation summary table.

Importance to Measure and Report

To meet this criterion, a measure's focus must address a high-impact area of care with a demonstrated performance gap and be a health outcome or evidence-based. Many practices are important for patient care but do not rise to the level of meeting the criteria for a national standard on quality performance.

Evidence

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

Some intermediate outcome measures with specific threshold values were supported by evidence primarily from observational studies. Although the Steering Committee agreed that the proposed assessment parameters should be used in patient care management, it noted the limitations of the evidence on which the performance measures were based. Observational studies can provide information on important associations that should be investigated further, but they cannot attribute causality. For example, observational studies that showed an association between dialysis dose and mortality led to the Hemodialysis (HEMO) randomized controlled trial that compared higher to lower dialysis dose (Kt/V) when delivered three times per week; however, the trial showed no difference in mortality between the two treatment groups.[5, 6] Furthermore, observational studies might lead to incorrect conclusions. For example, it was thought that taking hemoglobin to the normal range was the right approach for treating anemia, but it actually resulted in increased strokes and death.[7-10]Therefore, for topics without strong evidence for specific threshold values, the Committee recommended performance measures of assessment frequency or methods rather than the intermediate outcome.

Limited evidence was especially problematic for the proposed fluid management process measures. The Steering Committee agreed with the goal of those measures but thought that the

evidence provided insufficient basis for national standards for quality performance. The observational studies have confounding factors (e.g., dose and length of session). Although the processes are based on rational hypotheses and are appropriate for guiding clinical care, they should not be performance measures at this time. ~~Perhaps measures of other indices of fluid management (e.g., post-dialysis weight and blood pressure; problems during dialysis such as hypotension, cramping, vomiting; nutritional status; patient function and well-being) would be more appropriate~~

Performance Measures Versus Guidelines or Individual Patient Management

The Committee discussed the distinction between quality performance measures and clinical practice guidelines or individual patient management. As endorsed by NQF, quality performance measures are based on aggregated data for all relevant patients under the care of the facility or other entity whose performance is being measured and require standardization. Performance measures should focus on health outcomes or structures, processes, or intermediate outcomes that are based on strong clinical evidence of their effect on desired health outcomes. Guidelines and recommendations may include nuances and alternative treatment options to help to guide the care of individual patients such as monitoring trends over time and identifying individual factors that may indicate variation in treatment, which may be difficult to specify in a standard performance measure.

Target Population

Most of the measures specified either adult or pediatric ESRD patients. Separate measures are needed only if the measure focus (e.g., lab value, intervention) is different in the various subpopulations. Some measures directly or indirectly excluded home dialysis patients. The measure developers attributed the exclusion to a lack of data for home dialysis patients; however, the exclusion of this patient population should be based on ~~clinical~~ evidence and clearly stated as such ~~does not vary based on the dialysis location~~. A Committee member suggested that facilities and nephrologists should not be accountable for patients on home dialysis because they are less able to control their care. Other Committee members thought that facilities and nephrologists should be accountable for all patients under their care just as, for example, primary care

physicians are accountable for patients' LDL levels and home health agencies are accountable for patients' improvement in function measures. Patients should be included in measures based on the clinical evidence for the measure focus; excluding relevant patients may imply a different quality standard. So unless there was a good rationale for excluding home dialysis patients, the committee favored including home dialysis patients in the metrics.

The Committee identified possible modifications to the target populations/denominators for some measures, and this is an issue for harmonization of related measures. On a related note, a Committee member suggested that the targeted age group be specified in the denominator statement rather than just in the age field on the measure submission form.

Data Availability/Feasibility

All of the new measures submitted by the Centers for Medicare & Medicaid Services (CMS) ~~measures~~ are based on data that dialysis facilities will be required to submit to the CMS CROWNW~~w~~eb data system. Currently, the ~~T~~three l~~L~~argest ~~-~~dialysis organizations (DaVita, DCI and Fresenius), which account for roughly 70% of the ESRD population, ~~tend to have electronic systems that capture and~~ are approved to submit ~~transfer~~ batched ~~their~~ data to CROWNWeb~~,~~. ~~but small a~~All other smaller dialysis organizations (about 180) ~~rely more on~~ must perform monthly manual abstraction and data entry. The Centers for Disease Control and Prevention (CDC) infection measures are based on a National Health Safety Network (NHSN) data collection form, and the CMS infection measures require submission of much of the same information to CROWNweb. Both the CMS and CDC measures require facilities be able to identify patients with infection and blood culture results. The Steering Committee recommended that the CMS and CDC collaborate on one measure and ideally that facilities could submit data once and be included in both systems.

Related and Competing Measures

Many of the candidate consensus standards competed with each other or NQF-endorsed measures. The Steering Committee first evaluated each new measure on its own merits and then compared those measures that met the criteria for harmonization or selection of the best measure.

The Committee reviewed 10 measures on bloodstream infection and ultimately recommended 1 for endorsement. Many of the measures were redundant in one aspect or another, and many were untested and, therefore, could not demonstrate superiority over a tested measure.

Several measures presented potential harmonization issues with endorsed measures. The Steering Committee reviewed these measures and made recommendations that will be addressed during the upcoming endorsement maintenance project for renal disease. The Committee recommended that one measure should encompass both adult and pediatric patients, if possible, whenever the measure focus was the same. Comparison tables are provided in Appendix C.

RECOMMENDATIONS FOR ENDORSEMENT

This report presents the results of the evaluation of 32 measures considered under NQF's CDP. The comment period for the draft report occurred between March 24 and April 22, 2011. NQF received 161 comments from 32 organizations and individuals. A summary of the comments received and the Committee's responses are included in the evaluation summary table for each measure in the following sections. The complete text of the comments and responses are posted on the ESRD project web page.

Candidate Consensus Standards Recommended for Endorsement

Eleven measures are recommended for endorsement as voluntary consensus standards suitable for public reporting and quality improvement. Three of the 11 measures are recommended for time-limited endorsement because they were not yet tested for reliability and validity.

The evaluation summary tables follow the list of measures and summarize the results of the Steering Committee's evaluation of and voting on the candidate consensus standards that were

recommended for endorsement and the subsequent public and NQF member comments.

Hyperlinks are provided:

- from each listed measure to the evaluation summary table;
- from each summary table to the detailed measure specifications;
- from each summary table to the web page where all materials submitted by the developer or steward are posted; and
- from each summary table to the web page where the meeting and call summaries, transcripts, and recordings can be accessed.

The Steering Committee recommended the following candidate consensus standards for endorsement.

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 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

1418 Frequency of adequacy measurement for pediatric hemodialysis patients
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.

267
268

269

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)

1421 Method of adequacy measurement for pediatric hemodialysis patients
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.
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.

272

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

1423 Minimum spKt/V for pediatric hemodialysis patients
(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 *(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.

275

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

1425 Measurement of nPCR for pediatric hemodialysis patients
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 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.

276
277

278

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.

279

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)

1430 Lower limit of hemoglobin for pediatric patients
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 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.

280
281

282

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)

1433 Use of iron therapy for pediatric patients
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 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.

283
284

285

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

1438 Periodic assessment of post-dialysis weight by nephrologists
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. 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.

286
287

288

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)

1454 Proportion of patients with hypercalcemia
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 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%)

294

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

1463 Standardized hospitalization ratio for admissions
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 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.

295
296

297

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 and home 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;

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

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

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

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.

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

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

298

299

Candidate Consensus Standards Not Recommended for Endorsement

The following candidate consensus standards were not recommended for endorsement because they either did not meet NQF criteria (10 did not pass importance to measure and report; 3 had issues with other criteria), were not selected as the best among competing measures (7 infection measures), or were withdrawn by the measure developer (2 infection measures).

The evaluation summary tables follow the list of measures and summarize the results of the Steering Committee's evaluation of and voting on the candidate consensus standards that were not recommended for endorsement . Hyperlinks are provided:

- from each listed measure to the evaluation summary table;
- from each summary table to the web page where all materials submitted by the developer or steward are posted; and
- from each summary table to the web page where the meeting and call summaries, transcripts, and recordings can be accessed.

Anemia

Fluid Management

Mineral Metabolism

Hospitalization

Infection

Evaluation Summary—Candidate Consensus Standards Not Recommended for Endorsement

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.

346

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.

347
348

349

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

1428 Use of iron therapy when indicated
receiving an ESA. The Steering Committee did not identify any new information on which to reconsider its decision.

352

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.

353
354

355

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.

356
357

358

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.

359
360

361

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.

362
363

364

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.

365
366

367

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.

368
369

370

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.

371

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.

374

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.

375
376

377

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

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

380

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

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

381
382

383

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

1456 Bacteremia (rate)

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.

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

1456 Bacteremia (rate)
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 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.

384
385

386

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

1457 Access-related bacteremia (rate)
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 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.

387
388

389

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.

1455 Access-related bacteremia—using Medicare claims (rate)
Public and Member Comment No comments received on this measure.

390
391

392

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.

393
394

395

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.

396
397

398

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

1469 Clinically confirmed access-related infection (rate)
No comments received on this measure.

399
400

401

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.

402
403

ADDITIONAL RECOMMENDATIONS

Priorities for Performance Measurement of ESRD Care

The Steering Committee identified the following priority areas for measure development to facilitate improvement in quality of care and better outcomes for ESRD patients:

- Patient education for self-management (measured from the patient perspective)
- Patient-reported outcomes (e.g., "functional wellness")
- Care coordination and transitions of care
    - from chronic kidney disease (CKD) to ESRD (successful preparation for ESRD, i.e., optimal ESRD starts—preemptive kidney transplant, home dialysis, or in-center hemodialysis with a functioning arteriovenous (AV) fistula);
    - from pediatric to adults; and
    - between settings (e.g., in-center to home, skilled nursing facility to in-center, hospital to dialysis center)
- Appropriate use of more intensive therapy (including hemodialysis frequency and duration)
- Fluid management (The Committee recommended only one of the submitted fluid management measures.)
- End-of-life/palliative care
- Disparities
- Optimal management of other comorbid disease states (e.g., diabetes, hypertension, cardiovascular disease)
- Use of standard Kt/V so that hemodialysis patients on any treatment schedule can be included

Care Coordination and Transitions of Care

The Steering Committee identified a critical need for quality performance measures that address care coordination and transitions of care. The NQF-endorsed and recommended measures focus primarily on aspects of care after a patient enters ESRD and begins dialysis. However, about half of dialysis starts are problematic, occurring during a hospitalization without adequate

preparation, informed choice regarding modality of renal replacement therapy, or a functioning AV fistula.[1] Patients with CKD stage IV should be seen by a nephrologist, receive education about all renal replacement modalities, and make their choices prior to entering into end stage renal disease treatment. Then according to patient choices and when appropriate, these patients should be evaluated for kidney transplant ~~center~~, peritoneal dialysis, or home hemodialysis; have a functioning AV fistula for hemodialysis, ~~receive education about all modalities and make a choice prior to entering ESRD, and be on a transplant list if desired~~ or receive palliative care.

Concepts for Quality Performance Measures for ESRD Care

NQF-endorsed measures should focus on health outcomes or evidence-based structures, care processes, and intermediate clinical outcomes that lead to desired health outcomes for ESRD patients. Table 1 presents structures, processes, intermediate outcomes, and health outcomes that are indicative of the quality of care for ESRD. ***The items listed in Table 1 are not measures, rather they are concepts.*** Some of the concepts have associated NQF-endorsed measures or measures recommended for endorsement in this project; the other concepts require future measure development. The priority areas for measure development are bolded in Table 1. Although the table does not represent the entire continuum of CKD care, a few examples of measure concepts are included.

453 **Table 1: Structure, Process, and Outcome Concepts for Quality ESRD Care**

Structure →	Process →	Intermediate Outcome →	Outcome
PREVENTION			
	• Optimal management of hypertension – screening for eGFR, UAR • Avoidance of nephrotoxic medications	• Blood pressure (BP) • Kidney function	• Stage of CKD • No ESRD
TRANSITION TO ESRD			
• Medical/ healthcare home to coordi-nate and manage all care	• Preparation for ESRD • Early referral to prepare for renal replacement therapy (RRT) – nephrologist – vascular surgeon[a] – transplant center • Education for patient choice of RRT modality (peritoneal dialysis, hemodialysis, home dialysis, transplant, none/end-of-life)[a] • Management of nutrition, anemia, calcium/phosphorus/PTH in patients with CKD	***Optimal "healthy" ESRD Start Incident ESRD patients:*** • ***with preemptive kidney transplant*** • ***with hemodialysis start with a functioning AV fistula*** • ***with a dialysis start in-center or home (not in hospital)*** • ***who were seen 6 mo. prior by nephrologist, vascular surgeon*** • ***on transplant list*** • ***albumin ≥ 3.7*** • ***other clinical values as noted below***	***Incident ESRD patients:*** • ***with patient-reported choice of RRT***
ESRD CARE			
• Medical/ healthcare home to coordinate and manage all care	Evidence-based processes (evidence that process leads to desired outcomes) • Vascular access by fistula (or graft) for hemodialysis[a] • Sterile technique with vascular access • ***Adequate dialysis intensity (frequency and duration)*** • Erythropoietin stimulating agents for anemia • Iron therapy for anemia [b] pediatric • Restricted dietary salt intake Processes more distal to desired outcomes (require additional steps to influence outcomes and are NOT A PRIORITY FOR PERFORMANCE MEASUREMENT) • Assess anemia – iron stores[a] • Assess dialysis adequacy – frequency[a,b] – method[a,b]	Intermediate clinical outcome • Adequate dialysis dose achieved spKt/V ≥ 1.2[a,b] ***change to standard Kt/v*** • Hb at least 10 [a,b] • ***Fluid/weight management*** – weight gain/loss – adverse symptoms during dialysis (cramping, hypotension) – BP [before, during, after dialysis] • Serum calcium <10.2[b] • Serum phosphorous value • Growth and development within norms for age • Left ventricular function Other intermediate outcomes	**Health outcome** • Survival (mortality)[a] • ***Patient-reported outcomes—physical, psychosocial, role function*** • Freedom from infection including bloodstream infection (bacteremia)[b] • ***Health-related quality of life (KDQOL) – avg. score or improvement*** • Hospitalization

Structure →	Process →	Intermediate Outcome →	Outcome
	• Assess – serum calcium[a] – serum phosphorous[a] – PTH • Assess nPCR[b] • Assess weight[b] • Administer KDQOL[a] • Dietary counseling (including sodium) Other care processes applicable to patients with ESRD • **Care coordination and transitions** – **across settings[a]** – **pediatric to adult (across providers)** • Influenza immunization[a] • Other immunizations (HBV, pneumococcal) • ***Optimal management of diabetes[a]*** • ***Optimal management of CV risk factors[a]***	• ***Adherence to patient self-management behaviors (diet, sodium, fluid, infection, meds, CV risk factors, diabetes, etc.)*** Other intermediate outcomes applicable to patients with ESRD • LDL-C (<130, <100[a]) • HbA1c (< 8, >9[a]) • BP (<140/90, ≥140/90[a])	(proxy for deterioration in health status, complications) [b] • Kidney transplant outcomes Other ~~outcomes~~ • Patient ~~perception of~~ experience with care (CAHPS [a]) • ***Education received for patient self-management — measured from patient perspective (diet, sodium, fluid, infection, meds, CV, diabetes, etc.)*** • Patient-reported choice/autonomy • Efficiency (resource use plus quality)
END-OF-LIFE/PALLIATIVE CARE			
	Advanced directives	Symptom control	Patient experience with care

[a]NQF-endorsed measure(s).
[b]Recommended measure(s).
Note: Bolded text represents priority areas for measure development.

Processes More Distal to Desired Outcomes

Several NQF-endorsed, recommended, and proposed measures focus on practices that are not proximal to a desired outcome and require several additional steps before they can affect the desired outcome. For example, frequency or method of assessment of a lab value requires

appropriate interpretation of the value, identification of appropriate treatment/intervention, and appropriate administration of the treatment/intervention in order to influence the desired outcome. Likewise, measures of referral, education, or advice given by a provider also require additional steps for the desired impact on outcomes to be realized (e.g., patient understands, agrees, and acts on information).

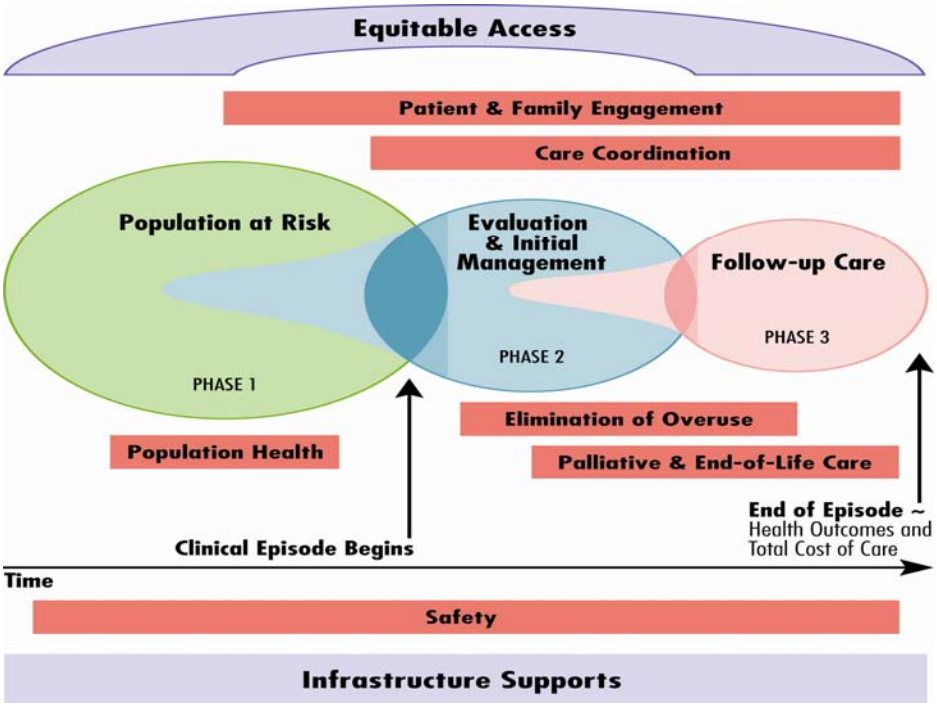
These more distal practices generally are considered necessary but not sufficient to achieve desired outcomes and/or drive improvements. Although there is usually expert consensus around these practices, they often are only supported by indirect evidence, that is, the evidence is for the specific proximal treatment/intervention or intermediate clinical outcome (e.g., hemoglobin >10). In general, these more distal processes are not a priority for measure development. Additionally, more proximal measures of patient-reported receipt of education, advice, or counseling, or patient behaviors such as adherence to medications and diet, are preferred.

Episode of Care Measurement Framework

NQF's generic episode of care measurement framework (Figure 1) can be used to conceptualize quality performance measures relevant to the development and progression of CKD. Phase I could represent patients at risk of chronic and end stage renal disease, Phase II could represent patients diagnosed with CKD including those transitioning to ESRD, and Phase III could represent the ongoing chronic care of patients with CKD and ESRD.

The measures submitted for this project focused entirely on care of ESRD patients on dialysis (Phase III). The upcoming endorsement maintenance project for renal disease will consider measures for the entire continuum of CKD as well as other renal diseases.

Figure1. Integrated Framework for Performance Measurement



In summary, the priority topics identified for measure development are critical to facilitate improvement in quality care and better outcomes for patients with ESRD. Some may present more difficult measurement challenges; however, specific measures that address the priority areas mentioned above should be the focus of development to assess the quality of care for ESRD patients.

NOTES

1. U.S.Renal Data System, *USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*, Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2010. Available at www.usrds.org/atlas.htm. Last accessed March 2011.
2. Vassalotti J, Stevens L, Levey AS, Testing for chronic kidney disease: A position statement from the National Kidney Foundation, *American Journal of Kidney Disease*, 2007;50(2):169-344:A1-A48.
3. National Quality Forum (NQF), *National Voluntary Consensus Standards for End Stage Renal Disease Care: A Consensus Report*, Washington, DC: National Quality Forum, 2008. Available at www.qualityforum.org/Publications/2008/03/National_Voluntary_Consensus_Standards_for_End_Stage_Renal_Disease_Care.aspx. Last accessed March 2011.
4. NQF, *Measure Evaluation Criteria*, Washington, DC: National Quality Forum, 2009. Available at www.qualityforum.org/docs/measure_evaluation_criteria.aspx. Last accessed March 2011.
5. Eknoyan G, Beck GJ, Cheung AK, et al., Effect of dialysis dose and membrane flux in maintenance hemodialysis, *N Engl J Med*, 2002;347(25):2010-2019.
6. Rocco MV, Cheung AK, Greene T, et al., The HEMO Study: applicability and generalizability, *Nephrol Dial Transplant*, 2005;20(2):278-284.
7. Demirjian SG, Nurko S, Anemia of chronic kidney disease: when normalcy becomes undesirable, *Cleve Clin J Med*, 2008;75(5):353-356.
8. Singh AK, Szczech L, Tang KL, et al., Correction of anemia with epoetin alfa in chronic kidney disease, *N Engl J Med*, 2006;355(20):2085-2098.
9. Solomon SD, Uno H, Lewis EF, et al., Erythropoietic response and outcomes in kidney disease and type 2 diabetes, *N Engl J Med*, 2010;363(12):1146-1155.
10. Winkelmayer WC, Confusion about the appropriate use of erythropoiesis-stimulating agents in patients undergoing maintenance dialysis, *Semin Dial*, 2010;23(5):486-491.

APPENDIX A—SPECIFICATIONS FOR THE NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR END STAGE RENAL DISEASE 2010

The following tables present the detailed measure specifications for the recommended consensus standards. All information presented here has been derived directly from the measure developers without modification or alteration (except where measure developers agreed to such modifications) and is current as of ~~March~~ May 2~~3~~5, 2011. All proposed voluntary consensus standards are open source, meaning they are fully accessible and disclosed.

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of all pediatric (less than 18 years) patients receiving in-center hemodialysis or home hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.
Type	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of patients in the denominator with monthly adequacy measurements (spKt/V) or its components in the calendar month.
Numerator Details	**Time Window:** The entire calendar month The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.
Denominator Statement	Number of pediatric patients (less than 18 years) receiving in-center hemodilaysis or home hemodialysis (irrespective of frequency of dialysis~~) who are in the facility and on hemodialysis for the entire study period..~~)..
Denominator Categories	Female; Male Pediatric patients less than 18 years old.
Denominator Details	**Time Window:** The entire calendar month. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. ~~In-center hemodialysishemodialysis~~Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.
Exclusions	~~Patients on home dialysis, patients not in the facility for the entire calendar month.~~None
Exclusion Details	~~See denominator details.~~ None.
Risk Adjustment	No risk adjustment necessary. N/A
Stratification	No stratification is required for this measure. Measure may be displayed separately for in-center hemodialysis patients and home hemodialysis patients.
Type Score	Rate/proportion better quality = higher score

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients
Algorithm	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. ~~In-center hemodialysis~~ Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. Home hemodialysis patients are determined by "Primary Dialysis Setting"= "Home" on the last day of the study period. The denominator will include all patients less than 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients. The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.

551

	1421 Method of adequacy measurement for pediatric hemodialysis patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of pediatric (less than 18 years old) in-center ~~HDHD~~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.
Type	Process
Data Source	Electronic Health/Medical Record CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of patients in the denominator for whom delivered HD dose for a single dialysis session was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified.
Numerator Details	**Time Window:** The entire calendar month. The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is 'Daugirdas II' OR 'UKM'.
Denominator Statement	Number of pediatric (less than 18 years old) in-center ~~HDHD~~hemodialysis patients (irrespective of frequency of dialysis) in the sample for analysis.
Denominator Categories	Female; Male Pediatric patients less than 18 years old.
Denominator Details	**Time Window:** The entire calendar month. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than 18 years old who are determined to be in-center hemodialysis patients.
Exclusions	Patients on home ~~dialysis, patients not in the facility for the entire calendar month.~~hemodialysis..
Exclusion Details	See denominator exclusions[I2].~~See denominator exclusions.~~
Risk	No risk adjustment necessary.

	1421 Method of adequacy measurement for pediatric hemodialysis patients
Adjustment	N/A
Stratification	No stratification is required for this measure.
Type Score	Rate/proportion better quality = higher score
Algorithm	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than 18 years old who are determined to be in-center hemodialysis patients. The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is 'Daugirdas II' OR 'UKM'.

552

553

554

	1423 Minimum spKt/V for pediatric hemodialysis patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of all pediatric (less than 18 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 to 1.2.
Type	Outcome
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
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 or equal to1.2.
Numerator Details	**Time Window:** 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 or equal to1.2. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.
Denominator Statement	Number of pediatric (less than 18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly.
Denominator Categories	Female; Male Pediatric patients less than 18 years old.
Denominator Details	**Time Window:** The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than 18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3 or 4. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.
Exclusions	Patients on home hemodialysis, patients on hemodialysis less than 90 days, patients receiving dialysis less than 3x/week or greater than 4x/week~~, patients not in the facility for the entire calendar month.~~.
Exclusion	Exclusions to this measure include patients receiving dialysis 5 times or more per week, as in those with diseases

	1423 Minimum spKt/V for pediatric hemodialysis patients
Details	such as oxalosis in whom frequent dialysis may result in minimal changes in urea clearance with the resulting low spKt/V for a single session. Patients receiving dialysis two times a week were also excluded as these patients likely have residual renal function, which is a component of clearance not currently captured.
Risk Adjustment	No risk adjustment necessary N/A
Stratification	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.
Type Score	Rate/proportion better quality = higher score
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than 18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3 or 4. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.

555

556

557

	1425 Measurement of nPCR for pediatric hemodialysis patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of pediatric (less than 18 years old) in-center ~~HDHD~~hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.
Type	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of patients in the denominator with monthly nPCR measurements.
Numerator Details	**Time Window:** The entire calendar month. The numerator will be determined by counting the patients in the denominator who meet one of the following criteria during the study month: npCR is populated AND "Date nPCR Collected" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated AND "Interdialytic Time" is populated.
Denominator Statement	Number of all pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis).
Denominator Categories	Female; Male Pediatric patients 18 years or younger.
Denominator Details	**Time Window:** The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than 18 years old. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.
Exclusions	Patients on home dialysis~~, patients not in the facility for the entire one-month study period.~~...

	1425 Measurement of nPCR for pediatric hemodialysis patients
Exclusion Details	See denominator exclusions.
Risk Adjustment	No risk adjustment necessary. N/A
Stratification	No stratification is required for this measure.
Type Score	Rate/proportion better quality = higher score
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than 18 years old. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator who meet one of the following criteria during the study month: npCR is populated AND "Date nPCR Collected" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated AND "Interdialytic Time" is populated.

558

559

560

	1424 Monthly hemoglobin measurement for pediatric patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of all pediatric (less than 18 years) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin.
Type	Process
Data Source	Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of pediatric (less than 18 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.
Numerator Details	**Time Window:** The entire calendar month. The numerator will be determined by counting all patients in the denominator who have values for 'Hemoglobin' and 'Hemoglobin Collection Date.'
Denominator Statement	All pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients.
Denominator Categories	Female; Male Pediatric patients age less than 18 years old.
Denominator Details	**Time Window:** The entire calendar month. Patients are ~~counted as being~~being included in the facility ~~for the entire calendar month~~month calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. All patients ~~in~~in under the ~~facility~~facility facility's care for the entire calendar month and are less than 18 years of age will be included in the denominator.
Exclusions	~~Patients who are not in the facility for the entire calendar month.~~None
Exclusion Details	~~See denominator exclusions.~~None.
Risk Adjustment	No risk adjustment necessary. N/A

	1424 Monthly hemoglobin measurement for pediatric patients
Stratification	No stratification is required for this measure. Measure may be displayed separately for in-center hemodialysis patients, home hemodialysis patients, and peritoneal hemodialysis patients.
Type Score	Rate/proportion better quality = higher score
Algorithm	Patients are ~~counted as being~~~~being~~included in the facility ~~for the entire calendar month~~~~month~~calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. All in-center HD, home HD, and PD patients ~~in~~under the ~~facility~~ facility's care for the entire calendar month and are less than18 years of age will be included in the denominator. The numerator will be determined by counting all patients in the denominator who have values for 'Hemoglobin' and 'Hemoglobin Collection Date.'

561

562

563

	1430 Lower limit of hemoglobin for pediatric patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients, with ESRD greater than or equal ~~to3to3~~to 3 months, who have a mean hemoglobin less than 10 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.
Type	Outcome
Data Source	Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients~~,~~ with End Stage Renal Disease (ESRD) greater than or equal to 3 months, who have a mean hemoglobin less than 10.0 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.
Numerator Details	**Time Window:** Three months from the start of the reporting period. The numerator will be determined by counting all patients in the denominator who have mean Hemoglobin values less than 10 g/dl.
Denominator Statement	All pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients with ESRD greater than or equal to 3 months.
Denominator Categories	Female; Male ~~PediatricPediatric~~pediatric patients less than 18 years old.
Denominator Details	**Time Window:** Three months from the start of the reporting period. Patients are ~~counted as being~~being included in the facility ~~for the entire calendar month~~month calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month, and the length of dialysis will be calculated as the difference between the first "Hemoglobin Collection Date" and "Date Regular Chronic Dialysis Began". Patients will be included in the denominator if they are ~~in~~under the ~~facility~~facility's care for the entire calendar month and their age is less than 18, length of dialysis is greater than or equal to 90 days, AND both "Hemoglobin" and "Hemoglobin Collection Date" are recorded in each of the 3 reporting months.
Exclusions	Patients on dialysis less than 3 months at the start of the reporting period~~, patients who are not in the facility for~~

	1430 Lower limit of hemoglobin for pediatric patients
	~~the entire one-month study period~~.
Exclusion Details	~~See denominator exclusions.~~ "Date Regular Chronic Dialysis Began" is greater than or equal to 3 months prior to the "Study Period Beginning Date."
Risk Adjustment	No risk adjustment necessary. N/A
Stratification	No stratification is required for this measure. Measure may be displayed separately for in-center hemodialysis patients, home hemodialysis patients, and peritoneal hemodialysis patients.
Type Score	Rate/proportion better quality = lower score
Algorithm	Patients are ~~counted as being~~being included in the facility ~~for the entire calendar month~~month calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month, and the length of dialysis will be calculated as the difference between the first "Hemoglobin Collection Date" and "Date Regular Chronic Dialysis Began". Patients will be included in the denominator if they are ~~in~~under the care of the facility for the entire calendar month and their age is less than 18, length of dialysis is greater than or equal to 90 days, AND both "Hemoglobin" and "Hemoglobin Collection Date" are recorded in each of the 3 reporting months. The numerator will be determined by counting all patients in the denominator who have mean Hemoglobin values less than 10 g/dl.

564

565

566

	1433 Use of iron therapy for pediatric patients
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Percentage of all pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients with hemoglobin less than 11.0 g/dL and in whom serum ferritin concentration was less than 100 ng/ml and TSATless than 20% who received IV iron or were prescribed oral iron within the following three months.
Type	Process
Data Source	Electronic clinical data CROWNWeb (Consolidated Renal Operations in a Web Enabled Network) http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
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 than 100 ng/mL and transferrin saturation (TSAT) less than 20% during the study period.
Numerator Details	**Time Window:** Three months following the first occurrence of serum ferritin less than 100 ng/mL and transferrin saturation (TSAT) less than 20%. The numerator will be determined by counting all patients in the denominator and "Intravenous IV Iron Prescribed" is populated OR "Oral Iron Prescribed" is populated.
Denominator Statement	All pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients ~~in the facility for the entire three-month reporting period~~ with hemoglobin less than 11 g/dL and in whom serum ferritin was less than 100 ng/mL and TSATless than 20% during the three month study period.
Denominator Categories	Female; Male Pediatric patients less than 18 years old.
Denominator Details	**Time Window:** Three months from the start of the reporting period. Patients are ~~counted as being~~being included in the facility ~~for the entire three-month reporting period~~period calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Patients who are ~~in~~under the ~~facility~~facility~~facility~~facility's care for the entire three-month study period with age less than 18 years will be included in the denominator if "Hemoglobin"less than 11 g/dl in any of the reporting months AND "Serum Ferritin"less than 100 ng/ml AND "TSAT"less than 20%, recorded in the same month ("Serum Ferritin Collection Date" = "Iron Saturation (TSAT) Percentage Collection Date") in any of the reporting months.
Exclusions	~~Patients who are not in the facility for the entire three-month study period.~~None.

	1433 Use of iron therapy for pediatric patients
Exclusion Details	See denominator exclusions.
Risk Adjustment	No risk adjustment necessary. N/A
Stratification	No stratification is required for this measure. Measure may be displayed separately for in-center hemodialysis patients, home hemodialysis patients, and peritoneal hemodialysis patients
Type Score	Rate/proportion better quality = higher score
Algorithm	Patients are ~~counted as being~~being included in the facility ~~for the entire three-month reporting period~~period calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Patients who are ~~in~~under the ~~facility~~facility~~facility~~facility's care for the entire three-month study period with age less than 18 years will be included in the denominator if "Hemoglobin"less than 11 g/dl in any of the reporting months AND "Serum Ferritin"less than 100 ng/ml, AND "TSAT"less than 20% recorded in the same reporting month ("Serum Ferritin Collection Date" = "Iron Saturation (TSAT) Percentage Collection Date") in any of the reporting months. The numerator will be determined by counting all patients in the denominator and "Intravenous IV Iron Prescribed" is populated OR "Oral Iron Prescribed" is populated.

567

568

569

	1438 Periodic assessment of post-dialysis weight by nephrologists
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	The proportion of in-center hemodialysis, 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.
Type	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
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.
Numerator Details	**Time Window:** The entire reporting calendar month. A data element recording "the date of the hemodialysis patient's last formal post-dialysis weight assessment by a nephrologist" will be included in the 2011 CROWNWeb national roll-out. Note that it is not necessary for the post-dialysis weight prescription to be changed monthly; however, a new prescription must be written monthly for compliance with the measure.
Denominator Statement	~~Number of patientspatients~~All adult and pediatric in ~~an outpatient dialysis facility undergoing chronic maintenance~~ center hemodialysis ~~(HD).~~, home hemodialysis, and peritoneal dialysis patients.
Denominator Categories	Female; Male Adult and pediatric patients.
Denominator Details	**Time Window:** The entire reporting calendar month. ~~Denominator includes only in-center HD patients.~~
Exclusions	None.
Exclusion Details	N/A
Risk Adjustment	No risk adjustment necessary. N/A

	1438 Periodic assessment of post-dialysis weight by nephrologists
Stratification	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. Similarly, the measure could be displayed separately for in-center hemodialysis patients, home hemodialysis patients, and peritoneal dialysis patients.
Type Score	Rate/proportion better quality = higher score
Algorithm	Patients are counted as being ~~inin~~under the care of the facility for the entire reporting month if "Admit Date" to the specified facility is prior or equal to the first day of the reporting month, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the reporting month. ~~Patients are counted as in-center HD patients if their in-center HD start date is less than or equal to the first day of the reporting month and their in-center HD end date is greater than or equal to the last day of the reporting month (or blank/null in the case the patient has not ended in-center HD).~~ Patients are included in the denominator if they were ~~continuously enrolled inin~~under the care of the dialysis facility ~~as an in-center HD patient~~ for the entire reporting month. Patients are included in the numerator if they are in the denominator and the facility reports that the patient received a new post-dialysis weight prescription in the reporting month, as indicated by the CROWNWeb data element recording the date of the last formal post-dialysis weight assessment by a nephrologist (see numerator details). The weight assessment occurred within the reporting month if the weight assessment date is less than or equal to the last day of the reporting month and the weight assessment date is also greater than or equal to the first day of the reporting month. The measure is calculated by dividing the numerator by the denominator.

570

571

572

	1454 Proportion of patients with hypercalcemia
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL
Type	Outcome
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of patients in the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL
Numerator Details	**Time Window:** Prior 3 months. If there are multiple serum calcium measurements during the month, the last value will be used for the calculation.
Denominator Statement	Number of adult (greater than or equal to 18 years old) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients ~~treated at at~~under the ~~outpatient~~outpatient~~t~~care of the 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.
Denominator Categories	Female; Male Adults 18 years or older
Denominator Details	**Time Window:** Prior 3 months. See above Denominator Statement.
Exclusions	None
Exclusion Details	N/A
Risk Adjustment	No risk adjustment necessary N/A
Stratification	~~N/AN/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.
Type Score	Rate/proportion better quality = lower score

	1454 Proportion of patients with hypercalcemia
Algorithm	Patients are included in the denominator if they are greater than or equal to 18 years old as of the first day of the most recent month of the study period, are on dialysis for more than 90 days as of the first day of the most recent month of the study period, are ~~in~~in under the care of the facility for at least 30 days as of the last day of the most recent month of the study period, and have at least one serum calcium measurement within the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the most recent month of the study period. The patient's time on dialysis will be determined by subtracting the patient's date regular Chronic Dialysis Began from the first day of the most recent month of the study period. Patients on dialysis are determined as follows: Primary Type of Dialysis is Hemodialysis, Home Hemodialysis, CAPD or CCPD in the most recent month of the study period. Patients ~~in aa~~under the care of the facility for at least 30 days are determined as follows: if the discharge date from the specified facility is missing/null or is after the last day of the most recent month of the study period, then the patient's time ~~in~~in under the care of the facility is calculated from the admit date to the last day of the most recent month of the study period; if the discharge date is prior to the last day of the most recent month of the study period, the patient is excluded from the calculation. In addition, the patient must have at least one valid measurement of total serum calcium within the study period. The numerator will be determined by counting the patients in the denominator who meet the following criteria: the average total serum calcium over the 3-month study period is greater than 10.2 mg/dL. If there is more than one serum calcium measurement within each month of the study period, the last value for the month shall be used for the calculation of the average.

573

574

575

	1463 Standardized hospitalization ratio for admissions
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244
Description	Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.
Type	Outcome
Data Source	Electronic administrative data/claims 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). http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912 http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912&intNumPerPage=10
Level	Facility/Agency
Setting	Dialysis Facility
Numerator Statement	Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.
Numerator Details	**Time Window:** One year. The numerator is calculated through use of Medicare claims data. When a claim is made for an inpatient hospitalization, the patient is identified and attributed to a dialysis facility following rules discussed below in the denominator details. The numerator is the count of all such hospitalizations over the reporting period. Once CROWNWeb is implemented nationally, the numerator could be calculated from data obtained from the CROWNWeb system. This would require the following data elements: #13.12.6.1 Hospitalizations: Indicates if a patient was hospitalized or went to the hospital emergency room #13.12.6.3 Hospital Admission Date: Indicates the date a dialysis patient was admitted to the hospital or taken to the emergency room The numerator would be calculated by counting the number of non-emergency room hospitalizations over the reporting period. This is indicated by CROWNWeb data element 13.12.6.1 Hospitalizations where only non-emergency room hospitalizations would be selected for the numerator calculation. CROWNWeb data element 13.12.6.3 Hospital Admission Date would be used to determine whether the hospitalization occurred within the reporting period and to determine which dialysis facility the patient is placed in at the time of hospitalization, following rules discussed below in the denominator details. The numerator is the count of all such hospitalizations over the reporting period.

	1463 Standardized hospitalization ratio for admissions
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.
Denominator Categories	Female; Male All
Denominator Details	**Time Window:** One year. For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for at least 60 days. If on day 91, the facility had treated a patient for fewer than 60 days, we wait until the patient reaches day 60 of treatment at that facility before attributing the patient to the facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remained assigned to their treatment facility for 60 days after withdrawal or recovery. Based on a risk adjustment model for the overall national hospitalization rates, we compute the expected number of hospitalizations that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations over patients and months yields the overall expected number of hospital admissions that would be expected given the specific patient mix and this forms the denominator of the measure. As implemented this measure is based on data from the Standard Information Management System (SIMS) to obtain patient attributions, and data on hospitalizations are obtained from Medicare claims data. Thus, the measure is relevant to patients covered by Medicare. Specific information on the implementation of this measure is described in the SHR Technical Documentation (http://www.dialysisreports.org/pdf/esrd/public/SHRdocumentation.pdf). Once CROWNWeb is implemented nationally, the denominator could be calculated as described above from the CROWNWeb data, using the following data elements: #4.1.37 Date Regular Chronic Dialysis Began: Indicates the date that the patient started regular course of dialysis. #4.3.5 Admit Date: Indicates the date of the patient's first dialysis treatment or home training date at the facility. #4.3.12 Discharge Date: Indicates the date that the facility discharges the patient. #4.3.13 Discharge Reason: Indicates the reason a patient was discharged from care at the facility. #13.12.6.1 Hospitalizations: Indicates if a patient was hospitalized or went to the hospital emergency room. #13.12.6.3 Hospital Admission Date: Indicates the date a dialysis patient was admitted to the hospital or taken to the emergency room #13.12.6.4 Hospital Discharge Date: Indicates the date a dialysis patient was discharged from the hospital
Exclusions	None

	1463 Standardized hospitalization ratio for admissions
Exclusion Details	N/A
Risk Adjustment	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, sex, diabetes, 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. http://www.dialysisreports.org/Methodology.aspx
Stratification	N/A
Type Score	Ratio better quality = lower score
Algorithm	http://www.dialysisreports.org/Methodology.aspx

576

577

578

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure (title will be changed to: Bloodstream Infection in Hemodialysis Outpatients)
Steward	Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31, Atlanta, GA 30333
Description	Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months
Type	Outcome
Data Source	Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis When using the NHSN form: 57.109 Dialysis Event http://www.cdc.gov/nhsn/psc_da_de.html#3 http://www.cdc.gov/nhsn/PDFs/pscManual/14_Tables_of_Instructions.pdf
Level	Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels
Setting	Dialysis Facility
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.
Numerator Details	**Time Window:** Cases are included if the positive blood culture occurs during a month The date of the event is based upon the date the blood culture was drawn. Information required: Number of positive blood culture events and event date. Definition: A positive blood culture is a blood culture that results in growth of 1 or more organisms. A new positive blood culture (not less than 21 days after a previous positive blood culture in the same patient) in a hemodialysis patient identified from blood cultures taken as an outpatient or within 1 calendar day after a hospital admission. Data specifications: When using the NHSN form, events are counted if the following field: ”patient with a positive blood culture” (on Form 57.109 under Event Details) is checked as being present. CMS will be identifying detailed specifications for CROWNweb.
Denominator Statement	Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit (estimated by those treated on the first 2 working days of the month).
Denominator Categories	Female; Male All ages
Denominator Details	**Time Window:** First 2 working days of each month Target population is all maintenance hemodialysis patients treated in a particular month in an outpatient hemodialysis center, estimated by the number of patients treated on the first 2 working days of the month.. Data specification: When using the NHSN form, the numeric value entered into the field labeled ”Total patients”

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure (title will be changed to: Bloodstream Infection in Hemodialysis Outpatients)
	(on Form 57.119) is used as the denominator. CMS will be identifying detailed specifications for CROWNweb.
Exclusions	Patients receiving inpatient hemodialysis and home hemodialysis are excluded.
Exclusion Details	The inpatient hemodialysis exclusion is only relevant for facilities that provide both outpatient (maintenance) and inpatient (acute or maintenance) hemodialysis. Patients who receive inpatient hemodialysis in the same facility are excluded. The home dialysis exclusion applies to all patients who are on home dialysis, including but not limited to home dialysis patients who are monitored by a dialysis facility.
Risk Adjustment	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. http://www.cdc.gov/nhsn/forms/57.119_DenomOutpatDialysis_BLANK.pdf
Stratification	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

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure (title will be changed to: Bloodstream Infection in Hemodialysis Outpatients)
	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.
Type Score	Rate/proportion better quality = lower score
Algorithm	1. Determine the number of bloodstream infection events in the unit for the month under surveillance (X) 2. Determine the outpatient hemodialysis facility patient census (i.e., denominator) for the month under surveillance (Y) 3. Divide X by Y and multiply this by 100 to determine the rate of bloodstream infections per 100 patient-months. Pooled mean rates are calculated by pooling the numerator over time (e.g., for an entire year or over multiple hemodialysis units) and dividing by the corresponding pooled denominator.

579

APPENDIX B—STEERING COMMITTEE

National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) Steering Committee

Peter Crooks, MD (Co-Chair)
Southern California Permanente Medical Group
Los Angeles, CA

Kristine Schonder, PharmD (Co-Chair)
University of Pittsburgh School of Pharmacy
Pittsburgh, PA

Constance Anderson, BSN, MBA
Northwest Kidney Centers
Seattle, WA

Sue Barnes, RN, BSN, CIC
Kaiser Permanente National Office
Oakland, CA

Jeffrey Berns, MD
University of Pennsylvania School of Medicine
Philadelphia, PA

Barbara Fivush, MD
Johns Hopkins University School of Medicine
Baltimore, MD

Jerry Jackson, MD
Nephrology Associates, PC
Birmingham, Alabama

Frederick Kaskel, MD, PhD
Children's Hospital at Montefiore
Bronx, NY

Myra Kleinpeter, MD, MPH
Tulane University School of Medicine
New Orleans, LA

Alan Kliger, MD
Hospital of St. Raphael/Yale University School of Medicine
New Haven, CT

Lisa Latts, MD, MSPH, MBA
WellPoint, Inc.
Denver, CO

Kathe LeBeau
Renal Support Network
Lathan, NY

Joseph V. Nally Jr., MD
Cleveland Clinic Foundation
Cleveland, OH

Andrew Narva, MD (ex officio)
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health
Bethesda, MD

Jessie Pavlinac, MS, RD, CSR, LD
Oregon Health & Science University
Portland, OR

Robert Provenzano, MD, FACP
DaVita
Detroit, Michigan

Joseph Vassalotti, MD, FASN
National Kidney Foundation
New York, NY

Ruben Velez, MD
Dallas Nephrology Associates
Dallas, TX

Roberta Wager, RN, MSN
American Association of Kidney Patients
San Antonio, TX

Harvey Wells
Dialysis Patient Advocate
Euless, TX

NQF Staff

Helen Burstin, MD, MPH
Senior Vice President of Performance Measures

Karen Pace, PhD, MSN
Senior Program Director

Lauren Richie, MA
Project Manager

Tenee Davenport
Project Analyst

APPENDIX C—COMPARISON OF RELATED MEASURES

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients	0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—monthly measurement of delivered dose
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
Description	Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month	Percentage of all adult (≥18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month
Type	Process	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php	Paper medical record/flow-sheet; Electronic administrative data/claims; Electronic Health/Medical Record
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients in the denominator with monthly adequacy measurements (spKt/V) or its components in the calendar month	Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients	0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—monthly measurement of delivered dose
Numerator Details	**Time Window:** The entire calendar month The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.	**Time Window:**
Denominator Statement	Number of pediatric patients (less than18 years) receiving in-center hemodialysis (irrespective of frequency of dialysis)who are in the facility and on hemodialysis for the entire study period	All adult (≥18 years old) HD patients in the sample for analyses
Denominator Categories	Female; Male Pediatric patients less than 18 years old	
Denominator Details	**Time Window:** The entire calendar month The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients.	**Time Window:**
Exclusions	Patients on home dialysis, patients not in the facility for the entire calendar month	
Exclusion Details	See denominator details.	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	No stratification is required for this measure.	
Type Score	Rate/proportion better quality = higher score	

	1418 Frequency of adequacy measurement for pediatric hemodialysis patients	0247 Hemodialysis adequacy clinical performance measure I: Hemodialysis adequacy—monthly measurement of delivered dose
Algorithm	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients. The numerator will be determined by counting the patients in the denominator who meet one of the following criteria in the one month study period: "Kt/V Hemodialysis Collection Date" is populated, AND "Kt/V Hemodialysis" is populated, OR "Kt/V Hemodialysis Collection Date" is populated, AND "BUN Pre-Dialysis" is populated, AND "BUN Post-Dialysis" is populated, AND "Pre-Dialysis Weight" is populated, AND "Pre-Dialysis Weight Unit of Measure" is populated, AND "Post-Dialysis Weight" is populated, AND "Post-Dialysis Weight Unit of Measure" is populated, AND "Delivered Minutes of BUN Hemodialysis Session" is populated.	

703
704

705

	1421 Method of adequacy measurement for pediatric hemodialysis patients	0248 Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
Description	Percentage of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period	Percentage of all adult (≥18 years old) in-center HD patients in the sample for analyses for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified.
Type	Process	Process
Data Source	Electronic Health/Medical Record CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Paper medical record/flow-sheet; Electronic administrative data/claims; Electronic Health/Medical Record
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
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	Number of patients in the denominator for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified
Numerator Details	**Time Window:** The entire calendar month. The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is 'Daugirdas II' OR 'UKM'.	**Time Window:**
Denominator Statement	Number of pediatric (less than18 years old) in-center HD patients (irrespective of frequency of dialysis) in the sample for analysis	All adult (≥18 years old) in-center HD patients in the sample for analyses
Denominator Categories	Female; Male Pediatric patients less than 18 years old	
Denominator Details	**Time Window:** The entire calendar month The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients	**Time Window:**

	1421 Method of adequacy measurement for pediatric hemodialysis patients	0248 Hemodialysis adequacy clinical performance measure II: Method of measurement of delivered hemodialysis dose
	less than18 years old who are determined to be in-center hemodialysis patients.	
Exclusions	Patients on home dialysis, patients not in the facility for the entire calendar month	
Exclusion Details	See denominator exclusions	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	No stratification is required for this measure.	
Type Score	Rate/proportion better quality = higher score	
Algorithm	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients less than18 years old who are determined to be in-center hemodialysis patients. The numerator will be determined by counting the patients in the denominator for whom Kt/V "Hemodialysis Method" is 'Daugirdas II' OR 'UKM'.	

706
707

708

	1423 Minimum spKt/V for pediatric hemodialysis patients	0250 Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
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	Percentage of all adult (≥18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the study period
Type	Outcome	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Electronic administrative data/claims
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
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	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2
Numerator Details	**Time Window:** 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 The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2	**Time Window:**
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	All adult (≥18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and whose RRF is unmeasured or whose RRF<2 ml/min/1.73m2 (if measured in the last three months)
Denominator Categories	Female; Male Pediatric patients less than 18 years old	
Denominator Details	**Time Window:** The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than18 years old who	**Time Window:**

	1423 Minimum spKt/V for pediatric hemodialysis patients	0250 Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
	have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3 or 4. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.	
Exclusions	Patients on home hemodialysis, patients on hemodialysisless than90 days, patients receiving dialysis less than3x/week or greater than 4x/week, patients not in the facility for the entire calendar month	Patients on HD less than 90 days. Patients with RRF >2 ml/min/1.73m2 (measured in the last three months)
Exclusion Details	Exclusions to this measure include patients receiving dialysis 5 times or more per week, as in those with diseases such as oxalosis in whom frequent dialysis may result in minimal changes in urea clearance with the resulting low spKt/V for a single session. Patients receiving dialysis two times a week were also excluded as these patients likely have residual renal function, which is a component of clearance not currently captured.	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	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.	
Type Score	Rate/proportion better quality = higher score	
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients less than18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3 or 4. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients	

	1423 Minimum spKt/V for pediatric hemodialysis patients	0250 Hemodialysis adequacy clinical performance measure III: Hemodialysis adequacy—HD adequacy CPM III: Minimum delivered hemodialysis dose
	are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.	

709
710

711

	1454 Proportion of patients with hypercalcemia	0261 Measurement of serum calcium concentration
Steward	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244	Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop S3-01-02, Baltimore, MD 21244-1850
Description	Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	Percentage of all adult peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month
Type	Outcome	Process
Data Source	Electronic clinical data CROWNWeb http://www.projectcrownweb.org/crown/index.php http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Paper medical record/flow-sheet; Electronic administrative data/claims
Level	Facility/Agency	Facility/Agency
Setting	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients in the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	Number of adult (≥18 years of age) dialysis patients included in denominator with serum calcium measured at least once within month
Numerator Details	**Time Window:** Prior 3 months. If there are multiple serum calcium measurements during the month, the last value will be used for the calculation	**Time Window:**
Denominator Statement	Number of adult (greater than or equal to18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one calcium measurement during the prior 90 days	All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis
Denominator Categories	Female; Male Adults 18 years or older	
Denominator Details	**Time Window:** Prior 3 months. See above Denominator Statement	**Time Window:**
Exclusions	None	Transient dialysis patients (in unit <30 days), pediatric patients and kidney transplant recipients with a functioning graft.
Exclusion Details	N/A	
Risk Adjustment	No risk adjustment necessary N/A	
Stratification	N/A	
Type Score	Rate/proportion better quality = lower score	
Algorithm	Patients are included in the denominator if they are greater than or equal to18 years old as of the first day of the most recent month of the study period, are on dialysis for more than 90 days as of the first day of the most recent month of the study period, are in the facility for at least 30 days as of the last day of the most recent month of the study period,	

	1454 Proportion of patients with hypercalcemia	0261 Measurement of serum calcium concentration
	and have at least one serum calcium measurement within the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the most recent month of the study period. The patient's time on dialysis will be determined by subtracting the patient's date regular Chronic Dialysis Began from the first day of the most recent month of the study period. Patients on dialysis are determined as follows: Primary Type of Dialysis is Hemodialysis, CAPD or CCPD in the most recent month of the study period. Patients in a facility for at least 30 days are determined as follows: if the discharge date from the specified facility is missing/null or is after the last day of the most recent month of the study period, then the patient's time in the facility is calculated from the admit date to the last day of the most recent month of the study period; if the discharge date is prior to the last day of the most recent month of the study period, the patient is excluded from the calculation. In addition, the patient must have at least one valid measurement of total serum calcium within the study period. The numerator will be determined by counting the patients in the denominator who meet the following criteria: the average total serum calcium over the 3-month study period is greater than 10.2 mg/dL. If there is more than one serum calcium measurement within each month of the study period, the last value for the month shall be used for the calculation of the average.	

712
713

714

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
Steward	Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion, 1600 Clifton Rd., MS A-31, Atlanta, GA 30333	Centers for Disease Control and Prevention, 1600 Clifton Rd, NE, Mailstop A-24, Atlanta, GA 30333
Description	Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months	Standardized Infection Ratio (SIR) of healthcare-associated, central line-associated bloodstream infections (CLABSI) among patients in intensive care units (ICUs) and Neonatal Intensive Care Units (NICUs)
Type	Outcome	Outcome
Data Source	Paper medical record/flow-sheet; Electronic Health/Medical Record; Lab data 57.119 Denominators for Outpatient Dialysis 57.109 Dialysis Event http://www.cdc.gov/nhsn/psc_da_de.html#3 http://www.cdc.gov/nhsn/PDFs/pscManual/14_Tables_of_Instructions.pdf	Electronic clinical data; Electronic Health/Medical Record; Lab data; Paper medical record/flow-sheet; Special or unique data NHSN Primary BSI collection form NHSN Denominator for ICU form NHSN Denominator for NICU form http://www.cdc.gov/nhsn/forms/57.108_PrimaryBSI_BLANK.pdf, http://www.cdc.gov/nhsn/forms/57.118_DenominatorICU_BLANK.pdf, http://www.cdc.gov/nhsn/forms/57.116_DenominatorNICU_BLANK.pdf Attachment Data Dictionary-634076366986069304.docx
Level	Facility/Agency; Population: national; Population: regional/network; Can be measured at all levels	Population: states; Facility/Agency; Population: national
Setting	Dialysis Facility	Hospital; Long term acute care hospital; Rehabilitation Facility
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.	Total number of observed healthcare-associated CLABSI among patients in ICUs and NICUs
Numerator Details	**Time Window:** Cases are included if the positive blood culture occurs during a month that the outpatient unit is performing surveillance Information required: Number of positive blood culture events and event date Definition: A new positive blood culture (not less than 21 days after a previous positive blood culture in the same patient) in a hemodialysis patient identified from blood cultures taken as an outpatient or within 1 calendar day after a hospital admission. Data specifications: Events are counted if the following field: "patient with a positive blood culture" (on Form 57.109 under Event Details) is checked as being present.	**Time Window:** 1. Definition of healthcare-associated Infection (HAI): Any infection reported to NHSN must meet the definition of an NHSN healthcare-associated infection, that is, a localized or systemic condition resulting from an adverse reaction to the presence of an infectious agent(s) or its toxin(s). There must be no evidence that the infection was present or incubating at the time of admission to the care setting. Clinical evidence may be derived from direct observation of the infection site or review of information in the patient chart or other clinical records. For certain, but not all, infection sites, a physician's or surgeon's diagnosis of infection derived from direct observation during a surgical operation, endoscopic examination, or other diagnostic studies or from clinical judgment may be an acceptable criterion for an NHSN

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		infection, unless there is compelling evidence to the contrary. 2. Definition of CLABSI: Primary bloodstream infections (BSI) are laboratory-confirmed bloodstream infections (LCBI) that are not secondary to an infection meeting CDC/NHSN criteria at another body site (see criteria in Chapter 17 CDC/NHSN Surveillance Definition. Report BSIs that are central line-associated (i.e., a central line or umbilical catheter was in place at the time of, or within 48 hours before, onset of the event). 3. Definition of Central line: An intravascular catheter that terminates at or close to the heart or in one of the great vessels which is used for infusion, withdrawal of blood, or hemodynamic monitoring. The following are considered great vessels for the purpose of reporting central-line BSI and counting central-line days in the NHSN system: Aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, common femoral veins, and in neonates, the umbilical artery/vein. NOTE: Neither the insertion site nor the type of device may be used to determine if a line qualifies as a central line. The device must terminate in one of these vessels or in or near the heart to qualify as a central line. 4. Infusion: The introduction of a solution through a blood vessel via a catheter lumen. This may include continuous infusions such as nutritional fluids or medications, or it may include intermittent infusions such as flushes or IV antimicrobial administration, or blood, in the case of transfusion or hemodialysis. 5. Umbilical catheter: A central vascular device inserted through the umbilical artery or vein in a neonate. 6. Temporary central line: A non-tunneled catheter. 7. Permanent central line: Includes o Tunneled catheters, including certain dialysis catheters o Implanted catheters (including ports) 8. CLABSI Criteria: • Laboratory-confirmed bloodstream infection (LCBI): Must meet one for the following criteria: Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures and organism cultured from blood is not related to an infection at another site. Criterion 2: Patient has at least one of the following signs or symptoms: fever (greater than 38oC), chills, or hypotension and signs and symptoms and positive laboratory results are not related to an infection at another site and common skin contaminant (i.e., diphtheroids [Corynebacterium spp.], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		spp.) is cultured from two or more blood cultures drawn on separate occasions. Criterion 3: Patient less than 1 year of age has at least one of the following signs or symptoms: fever (greater than 38oC core) hypothermia (less than36oC core), apnea, or bradycardia and signs and symptoms and positive laboratory results are not related to an infection at another site and common skin contaminant (i.e., diphtheroids [Corynebacterium spp.], Bacillus [not B. anthracis] spp., Propionibacterium spp., coagulase-negative staphylococci [including S. epidermidis], viridans group streptococci, Aerococcus spp., Micrococcus spp.) is cultured from two or more blood cultures drawn on separate occasions. 9. CDC Location: A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties. Each facility location that is monitored is "mapped" to one CDC Location. The specific CDC Location code is determined by the type of patients cared for in that area according to the 80% Rule. That is, if 80% of patients are of a certain type (e.g., pediatric patients with orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Pediatric Orthopedic Ward). 10. Location: The patient care area to which a patient is assigned while receiving care in the healthcare facility. 11. Location of attribution: The location to which the event is being attributed. 12. Date of event: In the case of an infection event, the date when the first signs or symptoms of infection (clinical evidence) appeared, or the date the specimen used to meet the infection criterion was collected, whichever came first. 13. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - • Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. • Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). • Limited: Hospital is used in the medical school's teaching program to only a limited extent.
Denominator Statement	Number of maintenance hemodialysis patients treated in the outpatient hemodialysis unit on the first 2 working days of the month	Total number of expected CLABSIs, calculated by multiplying the number of central line device days for each location under surveillance for CLABSI during the period by the CLABSI rate for the same types of locations obtained from the standard population. Central line device- day denominator data that are collected differ according to the

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		location of the patients being monitored. See 2a.8.
Denom Categories	Female; Male All ages	Female; Male Patients of all ages are included, from premature infant to adult.
Denominator Details	**Time Window:** First 2 working days of each month Target population is all maintenance hemodialysis patients treated on the first 2 working days of a particular month in an outpatient hemodialysis center. Data specification: The numeric value entered into the field labeled "Total patients" (on Form 57.119) is used as the denominator.	**Time Window:** The number of central line device days for the location under surveillance for CLABSI during the period is collected. This number is multiplied by the 2006 through 2008 standard population's CLABSI rate for the same type of location to obtain the number of expected CLABSIs. The expected number of CLABSIs is the sum across all location types during the period. The expected number of CLABSIs will be influenced by the number of central line device days in the facility and the CLABSI rate in the standard population; with low numbers of expected infections, it will be necessary to have a data sample of sufficient size to generate meaningful SIRs. Data required to calculate the denominator: 1. Number of appropriate device days for locations under CLABSI surveillance during the period 2. CLABSI rate per 1000 device days for the same location types from the identified population (2006 through 2008; see NHSN Report at http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF). 3. Definition of device days: Device days are used for denominators. Device day denominator data that are collected differ according to the location of the patients being monitored. a. For ICUs, the number of patients with one or more central lines of any type is collected daily, at the same time each day during the month. The totals for the month are entered. b. In NICUs, because of differing infection risks, the number of patients with central lines and those with umbilical catheters is collected daily, at the same time each day, during the month. If a patient had both an umbilical catheter and a central line, count the day only as an umbilical catheter day. For the NICU infants, patients are further stratified by birth weight in five categories since risk of BSI also varies by birthweight. 4. See 2a.3 for definitions of CDC location, location, and location of attribution. 5. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - a. Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. b. Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships).

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		c. Limited: Hospital is used in the medical school's teaching program to only a limited extent.
Exclusions	Patients receiving inpatient hemodialysis are excluded	1. Pacemaker wires and other nonlumened devices inserted into central blood vessels or the heart are excluded as central lines 2. Peripheral intravenous lines are excluded from this measure
Exclusion Details	The exclusion is only relevant for facilities that provide both outpatient (maintenance) and inpatient (acute or maintenance) hemodialysis. Patients who receive inpatient hemodialysis in the same facility are excluded.	See 2a.9
Risk Adjustment	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. http://www.cdc.gov/nhsn/forms/57.119_DenomOutpatDialysis_BLANK.pdf	CLABSI rates per 1000 central line device days are used to calculate the expected number of CLABSI for the denominator of the SIR. They are indirectly standardized rates accounting for the influence of length of stay and length of central line use, and are stratified by patient care location, adjusting for differences in patient morbidity and disease-specific variables which may influence CLABSI risk. See also 2a.4 and 2a.20. URL No such URL. Please see 2a.21.
Stratification	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	1. Facility-specific data for individual patient locations (i.e., bedsize of location, affiliation and level of affiliation with a medical school [Teaching statuses: major, graduate, limited, not affiliated - • Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services. • Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships). • Limited: Hospital is used in the medical school's teaching program to only a limited extent. 2. NICU location catheters are stratified by two types, central and umbilical lines. Numerator and denominator information is further stratified by five birthweight categories.

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
	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.	
Type Score	Rate/proportion better quality = lower score	Ratio
Algorithm	1. Determine the number of bloodstream infection events in the unit for the month under surveillance (X) 2. Determine the outpatient hemodialysis facility patient census (i.e., denominator) for the month under surveillance (Y) 3. Divide X by Y and multiply this by 100 to determine the rate of bloodstream infections per 100 patient-months. Pooled mean rates are calculated by pooling the numerator over time (e.g., for an entire year or over multiple hemodialysis units) and dividing by the corresponding pooled denominator.	The SIR is calculated as follows: 1. Identify the number of CLABSI in each location type 2. Total these numbers for an observed number of CLABSIs 3. Obtain the number of expected number of CLABSIs in the same location types for a standard population using the NHSN data report (http://www.cdc.gov/nhsn/PDFs/dataStat/2009NHSNReport.PDF) 4. Identify the number of expected CLABSIs for the facility based on its location types and numbers of central line device days: a. For each location type, multiply the number of central line device days experienced, by the expected CLABSI rate for that location b. Sum the number of expected CLABSIs from all locations

	1460 National Healthcare Safety Network (NHSN) bloodstream infection measure	PSM-001-10 National Healthcare Safety Network (NHSN) central line-associated bloodstream infection (CLABSI) outcome measure
		5. Divide the total number of observed CLABSI events ("2" above) by the "expected" number of CLABSI rates ("4.c." above). 6. Result = SIR (The NHSN analysis tool will perform the calculations once the patient infection data and denominator information are entered into the system.)

715

APPENDIX D— ESRD NQF-Endorsed® Measures

The full specifications for these measures can be found in the prior ESRD Report.

Measure ID Number/Title	Measure Description	Measure Steward
0252 Assessment of Iron Stores	Percentage of all adult (>=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb <11.0 g/dL in at least one month of the study period for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHr) are measured at least once in a three-month period for in-center hemodialysis patients, and at least twice during a six-month period for peritoneal dialysis patients and home hemodialysis patients.	Centers for Medicare & Medicaid Services
0370 Monitoring Hemoglobin Levels Below Target Mminimum	Percentage of all adult (>=18 years old) hemodialysis or peritoneal dialysis patients with ESRD >=3 months and who had Hb values reported for at least 2 of the 3 study months, who have a mean Hb <10.0 g/dL for a 3 month study period, irrespective of ESA use.	Centers for Medicare & Medicaid Services
0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose	Percentage of all adult (>= 18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month	Centers for Medicare & Medicaid Services
0248 Hemodialysis Adequacy Clinical Performance Measure II: Method of Measurement of Delivered Hemodialysis Dose	Percentage of all adult (>=18 years old) in-center HD patients in the sample for analyses for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified.	Centers for Medicare & Medicaid Services
0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy--Minimum Delivered Hemodialysis Dose	Percentage of all adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period.	Centers for Medicare & Medicaid Services
0250 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose	Percentage of all adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period.	Centers for Medicare & Medicaid Services
0323 Hemodialysis Adequacy/Plan of Care	Percentage of patient calendar months during the 12 month reporting period in which patients aged 18 years and older with a diagnosis of ESRD and receiving hemodialysis have a Kt/V>=1.2 AND have a Kt/V<1.2 with a documented plan of care	American Medical Association

Measure ID Number/Title	Measure Description	Measure Steward
0253 **Peritoneal Dialysis Adequacy- Measurement of total Solute Clearance at regular intervals**	Percentage of all adult (>= 18 years old) peritoneal dialysis patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period.	Centers for Medicare & Medicaid Services
0254 **Peritoneal Dialysis Adequacy- Calculate Weekly KT/Vurea in the Standard Way**	Percentage of all adult >= 18 years old) peritoneal dialysis patients who have: • Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance • Residual renal function (unless negligible [< 100 mL urine in 24 hours]) is assessed by measuring the renal component of Kt/Vurea and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance • Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method or the Haycock method of using actual body weight, during the four month study period.	Centers for Medicare & Medicaid Services
0318 **Peritoneal Dialysis Adequacy- Delivered Dose of peritoneal dialysis above minimum**	Percentage of all adult (>= 18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.	Centers for Medicare & Medicaid Services
0321 **Peritoneal Dialysis Adequacy/Plan of Care**	Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a Kt/V >=1.7 AND patients who have a Kt/V <1.7 with a documented plan of care 3 times a year (every 4 months) during the 12 month reporting period	American Medical Association
0261 **Measurement of Serum Calcium Concentration**	Percentage of all adult peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month	Centers for Medicare & Medicaid Services
0255 **Measurement of Serum Phosphorus Concentration**	Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.	Centers for Medicare & Medicaid Services
0256 **Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access**	Percentage of all adult (≥18 years old) dialysis patients with a serum ferritin ≥1,200 ng/mL or a transferrin saturation (TSAT) ≥50% on at least one simultaneous measurement during the 3-month study period who did not receive IV iron in the following 3 months	Centers for Medicare & Medicaid Services
0257 **Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)**	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles	Centers for Medicare & Medicaid Services

Measure ID Number/Title	Measure Description	Measure Steward
0251 **Vascular Access-Physician**	Percentage of all ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year who have a functional AV fistula (defined as two needles used) or do not have such a fistula but have been seen by a vascular surgeon for evaluation for permanent access at least once during the reporting year.	Kidney Care Quality Alliance/Kidney Care Partners
0262 **Vascular Access-Physician (b)**	Percentage of all ESRD patients aged 18 years and older receiving hemodialysis during the 12 month reporting year with a catheter after 90 days on dialysis who are seen by a vascular surgeon for evaluation for permanent access at least once during the 12-month reporting period.	Kidney Care Quality Alliance/Kidney Care Partners
0259 **Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula**	Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).	Society for Vascular Surgery
***0227** **Influenza Immunization**	Percentage of patients aged 18 years and older with a diagnosis of ESRD and receiving dialysis who received the influenza immunization during flu season (September through February)	Renal Physicians Association/ Physician Consortium for Performance Improvement
***0226** **Influenza Vaccination in the ESRD Population – Facilities**	Percentage of all ESRD patients aged 18 years and older receiving hemodialysis and peritoneal dialysis during the flu season (October 1 – March 31) who receive an influenza vaccination during the October 1 – March 31 reporting period.	Kidney Care Quality Alliance
0369 **Dialysis Facility Risk-adjusted Standardized Mortality Ratio (32) Level**	Risk-adjusted standardized mortality ratio for dialysis facility patients.	Centers for Medicare & Medicaid Services
0324 **Patient Education Awareness - Facilities**	Percentage of all ESRD patients 18 years and older with documentation regarding a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no treatment). Measured once a year.	Kidney Care Quality Alliance/Kidney Care Partners
0320 **Patient Education Awareness - Physician**	Percentage of all ESRD patients 18 years and older with documentation regarding a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no treatment). Measured once a year.	Kidney Care Quality Alliance/Kidney Care Partners
0260 **Assessment of Health-related Quality of Life (Physical & Mental Functioning)**	Percentage of dialysis patients who receive a quality of life assessment using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once per year.	RAND

Measure ID Number/Title	Measure Description	Measure Steward
0258 **CAHPS In-Center Hemodialysis Survey**	Percentage of patient responses to multiple testing tools. Tools include the In-Center Hemomdialysis Composite Score: The proportion of respondents answering each of response options for each of the items summed across the items within a composite to yield the composite measure score. (Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, Providing Information to Patients) Overall Rating: a summation of responses to the rating items grouped into 3 levels	Agency for Healthcare Research and Quality

*Note: Influenza-related measures **#0226 – Influenza immunization** and **#0227- Influenza vaccination in the ESRD population-facilities** will be reviewed during an upcoming Prevention Project.