This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized): Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) NQF Review #: 1426  NQF Project: End Stage Renal Disease

<table>
<thead>
<tr>
<th>MEASURE DESCRIPTIVE INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>De.1 Measure Title: Assessment of Iron Stores</td>
</tr>
<tr>
<td>De.2 Brief description of measure: Percentage of all adult (&gt;= 18 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.</td>
</tr>
<tr>
<td>1.1-2 Type of Measure: Process</td>
</tr>
<tr>
<td>De.3 If included in a composite or paired with another measure, please identify composite or paired measure N/A</td>
</tr>
<tr>
<td>De.4 National Priority Partners Priority Area: Population health</td>
</tr>
<tr>
<td>De.5 IOM Quality Domain: Effectiveness</td>
</tr>
<tr>
<td>De.6 Consumer Care Need: Living with illness</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CONDITIONS FOR CONSIDERATION BY NQF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:</td>
</tr>
<tr>
<td>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.</td>
</tr>
<tr>
<td>A.1 Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)? Yes</td>
</tr>
<tr>
<td>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</td>
</tr>
<tr>
<td>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</td>
</tr>
<tr>
<td>A.4 Measure Steward Agreement attached:</td>
</tr>
<tr>
<td>B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and</td>
</tr>
</tbody>
</table>

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least every 3 years. Yes, information provided in contact section 

C. The intended use of the measure includes both public reporting and quality improvement. 

Purpose: Public reporting, Internal quality improvement

D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement.

D.1 Testing: Yes, fully developed and tested

D.2 Have NQF-endorsed measures been reviewed to identify if there are similar or related measures? Yes

(for NQF staff use) Have all conditions for consideration been met?

Staff Notes to Steward (if submission returned):

Staff Notes to Reviewers (issues or questions regarding any criteria): 

Staff Reviewer Name(s):

1. IMPORTANCE TO MEASURE AND REPORT

Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact

(for NQF staff use) Specific NPP goal:

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, High resource use

1a.2

1a.3 Summary of Evidence of High Impact: The measure focus is important because prudent use of IV iron in dialysis patients improves management of anemia; lowers the dose of erythropoietin stimulating agent (ESA) needed to maintain the hemoglobin in the target range; avoids potential harm of excess iron administration; and encourages optimum utilization of pharmacologic and laboratory resources.


Comment [KP1]: 1a. The measure focus addresses: a specific national health goal/priority identified by NQF’s National Priorities Partners; OR a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).
Recent clinical trials provide evidence that targeting higher Hgb levels when treating anemia in patients with chronic kidney disease (CKD) may increase the risk of adverse outcomes. The Trial to Reduce Cardiovascular Endpoints with Aranesp Therapy (TREAT) study found higher rates of stroke, thromboembolism, and cancer-related deaths in patients with CKD and diabetes who were treated to the higher Hgb target. The Correction of Hemoglobin and Outcomes in Renal Insufficiency (CHOIR) study (CKD patients) [Singh AK, 2006] and the Normal Hematocrit study (dialysis patients at high cardiovascular risk) [Besarab A, 1998] both found higher rates of death and cardiovascular complications among patients.
treated to higher Hgb targets. Two meta-analyses, which included both dialysis and non-dialysis CKD studies, also supported these findings [Phrommintikul A, 2007; KDOQI, 2006]. Although the cause of higher event rates among patients randomized to higher Hgb targets remains incompletely understood, higher ESA doses have been implicated as a possible explanation, and recent opinion in the nephrology community has coalesced around strategies to limit ESA dose when possible. To this end, alternate methods to facilitate ESA-mediated erythropoiesis, and support Hgb levels with lower ESA doses, are increasingly recommended, and the judicious use of IV iron therapy remains central to this strategy [Kapoian T, 2008; Pizzi LT, 2008; Singh AK, 2010]. At the same time, the TEP recognizes evidence limitations with respect to long-term safety of IV iron therapy. As standard practice, IV iron dosing decisions are based on clinical measures of iron stores including ferritin and transferrin saturation (TSAT) levels. The proposed CPMs leave most treatment decisions about IV iron dosing to the judgment of the practitioner, with the exception of values notably out of normal range. For example, no judgment is made about IV iron dosing to patients with ferritin in the 100 to 1200 ng/mL range or with TSAT <50%.

1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom): Overall, Grade B evidence. Randomized clinical trials were conducted in mainly in CKD patients not on dialysis.

1c.6 Method for rating evidence: United States Preventive Services Task Force (USPSTF)

1c.7 Summary of Controversy/Contradictory Evidence: There is no controversy over the importance of routine iron assessment in dialysis patients.


1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):
### 3.2.1 Frequency of iron status tests

Iron status tests should be performed:
- Every month during initial ESA treatment
- At least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an ESA

### 3.2.2 Interpretation of iron status tests

Results of iron status tests, Hb, and ESA dose should be interpreted together to guide iron therapy.

#### 1c.10 Clinical Practice Guideline Citation


#### 1c.11 National Guideline Clearinghouse or other URL

N/A

#### 1c.12 Rating of strength of recommendation (also provide narrative description of the rating and by whom):

Kidney Disease Outcomes Quality Initiative (KDOQI) Anemia Guidelines are opinion-based.

#### 1c.13 Method for rating strength of recommendation (if different from USPSTF system, also describe rating and how it relates to USPSTF):

N/A

#### 1c.14 Rationale for using this guideline over others:

N/A

#### 2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)

### 2a. MEASURE SPECIFICATIONS

#### S.1 Do you have a web page where current detailed measure specifications can be obtained?

Yes

#### S.2 If yes, provide web page URL:

http://www.amjkidneydiseases.com/content/47/6_suppl/S16.full

#### 2a. Precisely Specified

- **2a.1 Numerator Statement** (Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome):
  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.

- **2a.2 Numerator Time Window** (The time period in which cases are eligible for inclusion in the numerator):
  Rolling three-month study period.

- **2a.3 Numerator Details** (All information required to collect/calculate the numerator, including all codes, logic, and definitions):
  The numerator will be determined by counting the patients in the denominator who meet the following criteria in the three-month study period: Serum Ferritin is populated, AND Iron Saturation Percentage is populated AND Serum Ferritin Collection Date is equal to Iron Saturation Percentage Collection Date.

**Comment [K7]:** USPSTF grading system http://www.ahrq.gov/clinic/uspstf/grades.htm:
- A - The USPSTF recommends the service. There is high certainty that the net benefit is substantial.
- B - The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.
- C - The USPSTF recommends against routinely providing the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
- D - The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.
- I - The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

**Comment [KP8]:** 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF’s Health Information Technology Expert Panel (HITEP).
### 2a.4 Denominator Statement (Brief, text description of the denominator - target population being measured):
All adult (>=18 years old) hemodialysis or peritoneal dialysis patients in the facility for the entire three-month study period.

### 2a.5 Target population gender: Female, Male

### 2a.6 Target population age range: Adults 18 years or older.

### 2a.7 Denominator Time Window (The time period in which cases are eligible for inclusion in the denominator):
Rolling three-month study period.

### 2a.8 Denominator Details (All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions):
Patients are included in the denominator if they are >= 18 years old, and on dialysis and in the facility for the entire study period.

The patient’s age will be determined by subtracting the patient’s date of birth from the first day of the study period. Patients in a facility and on dialysis for the entire study period 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 Primary Type of Treatment is Hemodialysis, continuous ambulatory peritoneal dialysis (CAPD) or continuous cycling peritoneal dialysis (CCPD) in each month of the study period.

### 2a.9 Denominator Exclusions (Brief text description of exclusions from the target population):
None.

### 2a.10 Denominator Exclusion Details (All information required to collect exclusions to the denominator, including all codes, logic, and definitions):
N/A

### 2a.11 Stratification Details/Variables (All information required to stratify the measure including the stratification variables, all codes, logic, and definitions):
N/A

### 2a.12-13 Risk Adjustment Type: No risk adjustment necessary

### 2a.14 Risk Adjustment Methodology/Variables (List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method):
N/A

### 2a.15-17 Detailed risk model available Web page URL or attachment:

### 2a.18-19 Type of Score: Rate/proportion

### 2a.20 Interpretation of Score: Better quality = Higher score

### 2a.21 Calculation Algorithm (Describe the calculation of the measure as a flowchart or series of steps):
Patients are included in the denominator if they are >= 18 years old, and on dialysis and in the facility for the entire study period.

The patient’s age will be determined by subtracting the patient’s date of birth from the first day of the study period. Patients in a facility and on dialysis for the entire study period 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 Primary Type of Treatment is Hemodialysis, CAPD or CCPD in each month of the study period.

The numerator will be determined by counting the patients in the denominator who meet the following criteria in the three-month study period: Serum Ferritin is populated, AND Iron Saturation Percentage is populated AND Serum Ferritin Collection Date is equal to Iron Saturation Percentage Collection Date.

### 2a.22 Describe the method for discriminating performance (e.g., significance testing):
The performance of the facility will be compared to state, Network and national performance.

### 2a.23 Sampling (Survey) Methodology If measure is based on a sample (or survey), provide instructions for...
obtaining the sample, conducting the survey and guidance on minimum sample size (response rate): N/A

2a.24 Data Source (Check the source(s) for which the measure is specified and tested)
Electronic clinical data

2a.25 Data source/data collection instrument (identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.):
CROWNWeb


2a.32-35 Level of Measurement/Analysis (Check the level(s) for which the measure is specified and tested)
Facility/Agency

2a.36-37 Care Settings (Check the setting(s) for which the measure is specified and tested)
Dialysis Facility

2a.38-41 Clinical Services (Healthcare services being measured, check all that apply)
Dialysis

<table>
<thead>
<tr>
<th>TESTING/ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2b. Reliability testing</td>
</tr>
</tbody>
</table>

2b.1 Data/sample (description of data/sample and size): The measure has not been tested for reliability.

2b.2 Analytic Method (type of reliability & rationale, method for testing):
Since the data are submitted electronically, we anticipate highly reliable measures. No elements for the measure would be abstracted from records, and no elements would be susceptible to inter-rater variability. Reliability testing of the CROWNWeb data has not yet been performed although monthly reports are currently being distributed to facilities participating in Phase 1 and 2 to compare the metrics to their own data.

2b.3 Testing Results (reliability statistics, assessment of adequacy in the context of norms for the test conducted): N/A

<table>
<thead>
<tr>
<th>2c. Validity testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>2c.1 Data/sample (description of data/sample and size): N/A</td>
</tr>
</tbody>
</table>

2c.2 Analytic Method (type of validity & rationale, method for testing):
Face validity is the only validity assessed, therefore testing is not applicable.

2c.3 Testing Results (statistical results, assessment of adequacy in the context of norms for the test conducted): N/A

2d. Exclusions Justified

2d.1 Summary of Evidence supporting exclusion(s): N/A

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2d.2</td>
<td>Citations for Evidence: N/A</td>
</tr>
<tr>
<td>2d.3</td>
<td>Data/sample (description of data/sample and size): N/A</td>
</tr>
<tr>
<td>2d.4</td>
<td>Analytic Method (type analysis &amp; rationale): N/A</td>
</tr>
<tr>
<td>2d.5</td>
<td>Testing Results (e.g., frequency, variability, sensitivity analyses): N/A</td>
</tr>
<tr>
<td>2e.1</td>
<td>Data/sample (description of data/sample and size): N/A</td>
</tr>
<tr>
<td>2e.2</td>
<td>Analytic Method (type of risk adjustment, analysis, &amp; rationale): N/A</td>
</tr>
<tr>
<td>2e.3</td>
<td>Testing Results (risk model performance metrics): N/A</td>
</tr>
<tr>
<td>2e.4</td>
<td>If outcome or resource use measure is not risk adjusted, provide rationale: N/A</td>
</tr>
<tr>
<td>2f.1</td>
<td>Data/sample from Testing or Current Use (description of data/sample and size): N/A</td>
</tr>
<tr>
<td>2f.2</td>
<td>A test calculation of the measure was performed using CROWNWeb Phase II data from July-September 2009. The calculation included data for 3384 facilities.</td>
</tr>
<tr>
<td>2f.3</td>
<td>Methods to identify statistically significant and practically/meaningfully differences in performance (type of analysis &amp; rationale): The distribution of percent of patients meeting measure criteria by facility was examined.</td>
</tr>
<tr>
<td>2f.4</td>
<td>If disparities in care have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A</td>
</tr>
<tr>
<td>2g.1</td>
<td>Data/sample (description of data/sample and size): N/A</td>
</tr>
<tr>
<td>2g.2</td>
<td>Analytic Method (type of analysis &amp; rationale): N/A</td>
</tr>
<tr>
<td>2g.3</td>
<td>Testing Results (e.g., correlation statistics, comparison of rankings): N/A</td>
</tr>
<tr>
<td>2h.1</td>
<td>If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A</td>
</tr>
<tr>
<td>2h.2</td>
<td>If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A</td>
</tr>
</tbody>
</table>

**TAP/Workgroup:** What are the strengths and weaknesses in relation to the subcriteria for Scientific Acceptability of Measure Properties?

**Steering Committee:** Overall, to what extent was the criterion, Scientific Acceptability of Measure Properties, met?

**Rating:** C= Completely; P= Partially; M= Minimally; N= Not at all; NA= Not applicable
3. Usability

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

3a. Meaningful, Understandable, and Useful Information

3a.1 Current Use: In use

3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years):

N/A

3a.3 If used in other programs/initiatives (If used in quality improvement or other programs/initiatives, provide name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years):

A similar measure is calculated in the monthly CROWNWeb Phase III CPM reporting (Anemia Management CPM llb: Assessment of Iron Stores). Our new proposed process measure has been proposed to replace CPM llb.

3a.4 Data/sample (description of data/sample and size): N/A

3a.5 Methods (e.g., focus group, survey, QI project): N/A

3a.6 Results (qualitative and/or quantitative results and conclusions): N/A

3b/3c. Relation to other NQF-endorsed measures

3b.1 NQF # and Title of similar or related measures:

NQF #0252 Phase III ESRD CPM Anemia Management CPM llb: Assessment of Iron Stores

(for NQF staff use) Notes on similar/related endorsed or submitted measures:

3b. Harmonization

If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population):

3b.2 Are the measure specifications harmonized? If not, why?

Yes. Our new proposed process measure has been proposed to replace CPM llb.

3c. Distinctive or Additive Value

3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:

Revisions to current CPM:

- The specification that serum ferritin and TSAT be measured on the same day. This requirement is based on the rationale that the clinical utility of serum ferritin and TSAT is highest when measured and interpreted together. Based on CROWNWeb test data, 99% of patients with ferritin and TSAT measured within one month had the measurements on the same day.
- The specification to measure serum ferritin and TSAT for all patients, not just those receiving ESAs or with Hgb <11 g/dL:
  - This approach is consistent with the 2006 KDOQI recommendations. It is also consistent with the

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audiences(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [K24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., influenza immunization of patients in hospitals or nursing homes), or related measures for the same target population (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).
Occasionally, patients have Hgb levels in the normal or near-normal range without requiring any long-term pharmacologic (ESA or iron) therapy. While some practitioners may not measure iron stores routinely in these patients, the prevalence of this condition is very low, estimated at 2% or less of dialysis patients.

Preliminary CROWNWeb data indicate that ferritin and TSAT levels are measured in ~95% of patients, and that this practice does not vary by Hgb level.

Dropping the use of reticulocyte hemoglobin content (CHr) as an alternative to TSAT levels for assessment or iron stores:

- Although the use of CHr was added to the 2006 CPM to harmonize with the KDOQI guidelines, the utility of measuring CHr instead of TSAT for the assessment of iron stores is uncertain.
- Additionally, the practice of CHr measurement remains uncommon in US dialysis facilities. Based on preliminary CROWNWeb data reported for 226,210 patients in December 2009, 204,905 (91%) had TSAT values; 10,363 (4.6%) had CHr values; and only 545 (0.2%) had CHr but not TSAT values. The addition of CHr to the CPM can be considered should future data support its utility, and its measurement becomes more common.

5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:

Revisions to current CPM:

- The specification that serum ferritin and TSAT be measured on the same day. This requirement is based on the rationale that the clinical utility of serum ferritin and TSAT is highest when measured and interpreted together. Based on CROWNWeb test data, 99% of patients with ferritin and TSAT measured within one month had the measurements on the same day.
- The specification to measure serum ferritin and TSAT for all patients, not just those receiving ESAs or with Hgb <11 g/dL:
  - This approach is consistent with the 2006 KDOQI recommendations. It is also consistent with the current trend in practice to limit ESA therapy when possible, as judicious use of intravenous iron decreases ESA requirements and in some patients can support Hgb levels without the need for ESA therapy for several months or more.
  - Occasionally, patients have Hgb levels in the normal or near-normal range without requiring any long-term pharmacologic (ESA or iron) therapy. While some practitioners may not measure iron stores routinely in these patients, the prevalence of this condition is very low, estimated at 2% or less of dialysis patients.
  - Preliminary CROWNWeb data indicate that ferritin and TSAT levels are measured in ~95% of patients, and that this practice does not vary by Hgb level.
- Dropping the use of reticulocyte hemoglobin content (CHr) as an alternative to TSAT levels for assessment or iron stores:
  - Although the use of CHr was added to the 2006 CPM to harmonize with the KDOQI guidelines, the utility of measuring CHr instead of TSAT for the assessment of iron stores is uncertain.
  - Additionally, the practice of CHr measurement remains uncommon in US dialysis facilities. Based on preliminary CROWNWeb data reported for 226,210 patients in December 2009, 204,905 (91%) had TSAT values; 10,363 (4.6%) had CHr values; and only 545 (0.2%) had CHr but not TSAT values. The addition of CHr to the CPM can be considered should future data support its utility, and its measurement becomes more common.
### Data Generated as a Byproduct of Care Processes

**4a.** How are the data elements that are needed to compute measure scores generated?

Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition)

**Rating:**
- C=Completely
- P=Partially
- M=Minimally
- N=Not at all
- NA=Not applicable

**Comment [KP26]:** For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

### Electronic Sources

**4b.** Are all the data elements available electronically? (Elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims)

**Rating:**
- C=Completely
- P=Partially
- M=Minimally
- N=Not at all
- NA=Not applicable

**Comment [KP27]:** The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

**Comment [KP28]:** Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

### Exclusions

**4c.** Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?

- No
- If yes, provide justification.

**Rating:**
- C=Completely
- P=Partially
- M=Minimally
- N=Not at all
- NA=Not applicable

**Comment [KP29]:** Identify susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

### Data Collection Strategy/Implementation

**4d.** Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/implementation issues:

Data are from the electronic CROWNWeb system, and are minimally susceptible to inaccuracies and errors.

**Rating:**
- C=Completely
- P=Partially
- M=Minimally
- N=Not at all
- NA=Not applicable

**Comment [KP30]:** Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).
### RECOMMENDATION

(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.

<table>
<thead>
<tr>
<th>Steering Committee: Do you recommend for endorsement?</th>
<th>Y</th>
<th>N</th>
<th>A</th>
</tr>
</thead>
</table>

### CONTACT INFORMATION

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2. **Point of Contact**
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3. **Measure Developer if different from Measure Steward**
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5. **Submitter if different from Measure Steward POC**
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6. **Additional organizations that sponsored/participated in measure development**

### ADDITIONAL INFORMATION

- **Workgroup/Expert Panel involved in measure development**
  - Dr. David VanWyck, panel chair (Vice President, Clinical Services, DaVita)
  - Dr. Lynda Szczech (Duke University School of Medicine, Durham, NC)
  - Dr. John Stivelman (University of Washington School of Medicine/Northwest Kidney Centers, Seattle, WA)
  - Dr. David Gilbertson (USRDS, Minneapolis, MN)
  - Dr. Michael Lazarus (Senior Executive Vice President, Fresenius Medical Care NA)
  - Dr. Ajay Singh (Brigham and Women's Hospital, Boston, MA)
  - Dr. Bruce Robinson, Moderator (Arbor Research Collaborative for Health, Ann Arbor, MI)
  - Flannery Campbell, MS, Analyst (University of Michigan, Ann Arbor, MI)

- **If adapted, provide name of original measure:**
- **If adapted, provide original specifications URL or attachment**

- **Measure Developer/Steward Updates and Ongoing Maintenance**
  - **Year the measure was first released:**
  - **Month and Year of most recent revision:**
  - **What is your frequency for review/update of this measure?** 3 years
  - **When is the next scheduled review/update for this measure?** 2013

- **Copyright statement/disclaimers:**
- **Additional Information web page URL or attachment:**

**Date of Submission (MM/DD/YY): 09/27/2010**
4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status - patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

2d. Clinically necessary measure exclusions are identified and must be:
• supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion; AND
• a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus; AND
• precisely defined and specified:
  – if there is substantial variability in exclusions across providers, the measure is specified so that exclusions are computable and the effect on the measure is transparent (i.e., impact clearly delineated, such as number of cases excluded, exclusion rates by type of exclusion);
if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).