

# NATIONAL QUALITY FORUM

## Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the [submitting standards web page](#).

NQF #: <b>0252</b> NQF Project: <b>Renal Endorsement Maintenance 2011</b>
(for Endorsement Maintenance Review) Original Endorsement Date: <b>Nov 15, 2007</b> Most Recent Endorsement Date: <b>Nov 15, 2007</b>
<b>BRIEF MEASURE INFORMATION</b>
De.1 Measure Title: <b>Assessment of Iron Stores</b>
Co.1.1 Measure Steward: <b>Centers for Medicare &amp; Medicaid Services</b>
De.2 Brief Description of Measure: <b>Percentage of all adult (&gt;=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb &lt;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, peritoneal dialysis patients, and home hemodialysis patients.</b>
2a1.1 Numerator Statement: <b>Number of dialysis patients in the denominator 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, peritoneal dialysis patients, and home hemodialysis patients.</b>
2a1.4 Denominator Statement: <b>All adult (&gt;=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb &lt;11.0 g/dL in at least one month of the study period. The study period consists of 3 consecutive months for in-center hemodialysis patients, peritoneal dialysis patients and home hemodialysis. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for this calculation.</b>
2a1.8 Denominator Exclusions: <b>Acute HD, transient dialysis patients (seen at the specific center for less than 30 days), and kidney transplant patients are excluded from the calculation this CPM.</b>
1.1 Measure Type: <b>Process</b> 2a1. 25-26 Data Source: <b>Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</b> 2a1.33 Level of Analysis: <b>Facility</b>
1.2-1.4 Is this measure paired with another measure? <b>No</b>
De.3 If included in a composite, please identify the composite measure ( <i>title and NQF number if endorsed</i> ):

<b>STAFF NOTES</b> ( <i>issues or questions regarding any criteria</i> )
Comments on Conditions for Consideration:
Is the measure untested? Yes <input type="checkbox"/> No <input type="checkbox"/> If untested, explain how it meets criteria for consideration for time-limited endorsement:
1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure ( <i>check De.5</i> ): 5. Similar/related <b>endorsed</b> or submitted measures ( <i>check 5.1</i> ): Other Criteria:
Staff Reviewer Name(s):

**1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT**

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See [guidance on evidence](#).

*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: H  M  L  I

*(The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.)*

De.4 Subject/Topic Areas (Check all the areas that apply): Renal : End Stage Renal Disease (ESRD)

De.5 Cross Cutting Areas (Check all the areas that apply):

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, High resource use, Patient/societal consequences of poor quality, Severity of illness

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact (Provide epidemiologic or resource use data):

The kidneys are responsible for the production of the hormone erythropoietin, which stimulates the production of red blood cells in the bone marrow. Kidney disease frequently results in a deficiency in this hormone, leading to the development of anemia, particularly after reaching the reduced level of kidney function that requires dialysis. Hemodialysis also results in some blood loss during each treatment session. The benefit to patients of correcting anemia is primarily related to quality of life - increased vitality, less fatigue, less depression, and improved physical symptoms - and the avoidance of blood transfusions (KDOQI 2006). The use of erythropoiesis-stimulating agents (ESAs) and iron supplementation are accepted and effective therapies for correcting anemia in people with chronic kidney disease and end-stage renal failure. If iron stores are not sufficient, the increase in erythropoietin will not result in an increase in red blood cells and hemoglobin. Therefore, assessment of iron stores is important to ensure the success of ESA therapy. Testing iron status also assesses the potential contribution of iron deficiency to the patient's anemia and the potential need for further evaluation of gastrointestinal bleeding. At the end of 2005, there were 485,012 patients being dialyzed, 106,912 of whom were new (incident) ESRD patients (USRDS 2007 ADR, Tables D.1)

1a.4 Citations for Evidence of High Impact cited in 1a.3: KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, American Journal of Kidney Diseases, 49(Supplement 3): S1-S146 (May 2006).

USRDS 2007 ADR, Tables D.1

1b. Opportunity for Improvement: H  M  L  I

*(There is a demonstrated performance gap - variability or overall less than optimal performance)*

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:

If iron stores are not sufficient, the increase in erythropoietin will not result in an increase in red blood cells and hemoglobin. Testing iron status also assesses the potential contribution of iron deficiency to the patient's anemia and the potential need for further evaluation of gastrointestinal bleeding. Therefore, continued implementation of this measure is needed to ensure the success of ESA therapy.

1b.2 Summary of Data Demonstrating Performance Gap (Variation or overall less than optimal performance across providers):

**[For Maintenance - Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.]**

Analysis of CROWNWeb data from January 2010 indicated the mean percentage of patients with Assessment of Iron Stores, HD and PD was 97% (SD=10%). Distribution: Min=0%, Max=100%, 1st quartile=97%, median=100%, 3rd quartile=100%.

1b.3 Citations for Data on Performance Gap: **[For Maintenance - Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included]**

Performance gap analyses were performed using CROWNWeb data from January 2010. There were 3436 facilities and a total of 293,694 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

**1b.4 Summary of Data on Disparities by Population Group:** [*For Maintenance – Descriptive statistics for performance results for this measure by population group*]

For each population group analysis, the percent of patients (e.g. percent of females) was divided into quintiles and the performance measure was calculated for each quintile. No disparities in performance were observed by race, sex, ethnicity, or age. The range in percent of patients with assessment of iron stores across quintiles is presented below.

Population Group (Range):

Females (94.2%-94.8%)

Black (94.0%-94.9%)

White (94.1%-94.9%)

Hispanic (93.6%-94.8%)

Age (94.3%-94.8%)

**1b.5 Citations for Data on Disparities Cited in 1b.4:** [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

CROWNWeb data from July 2009-December 2009 were analyzed. The number of facilities ranged from 3398-3453 and the total number of patients per month ranged from 263,743 - 290,713.

**1c. Evidence** (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)  
 Is the measure focus a health outcome? Yes  No  **If not a health outcome, rate the body of evidence.**

Quantity: H  M  L  I  Quality: H  M  L  I  Consistency: H  M  L  I

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes <input type="checkbox"/>
L	M-H	M	Yes <input type="checkbox"/> IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No <input type="checkbox"/>
M-H	L	M-H	Yes <input type="checkbox"/> IF potential benefits to patients clearly outweigh potential harms: otherwise No <input type="checkbox"/>
L-M-H	L-M-H	L	No <input type="checkbox"/>

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service

Does the measure pass subcriterion1c?  
 Yes  IF rationale supports relationship

**1c.1 Structure-Process-Outcome Relationship** (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):

The measure focus is the process of assessing iron stores in ESRD dialysis patients.

**1c.2-3 Type of Evidence** (*Check all that apply*):

Clinical Practice Guideline

**1c.4 Directness of Evidence to the Specified Measure** (*State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population*):

The body of evidence show a relationship between hemoglobin levels above the target minimum and improved mortality and morbidity. This measure focus is on the assessing iron stores in ESRD dialysis patients.

**1c.5 Quantity of Studies in the Body of Evidence** (*Total number of studies, not articles*): 3

**1c.6 Quality of Body of Evidence** (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The studies consist of two

randomized clinical trials and one determination by FDA's panel of experts' opinion.

1c.7 Consistency of Results across Studies (Summarize the consistency of the magnitude and direction of the effect): Results were consistent across studies.

1c.8 Net Benefit (Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms):

The body of evidence show a relationship between hemoglobin levels above the target minimum and improved mortality and morbidity.

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? Yes

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: Two of the studies were graded B and one was not graded.

1c.11 System Used for Grading the Body of Evidence: GRADE

1c.12 If other, identify and describe the grading scale with definitions:

1c.13 Grade Assigned to the Body of Evidence: An overall grade was not assigned.

1c.14 Summary of Controversy/Contradictory Evidence: No contradictory evidence.

1c.15 Citations for Evidence other than Guidelines (Guidelines addressed below):

(1) Singh AK, Szczech L, Tang KL, et al. Correction of anemia with epoetin alfa in chronic kidney disease. New England Journal of Medicine, 355: 2085-2098, 2006.

(2) Drueke TB, Locatelli F, Clyne N, et al. Normalization of hemoglobin level in patients with chronic kidney disease and anemia. New England Journal of Medicine, 355: 2071-2084, 2006.

(3) U.S. Food and Drug Administration. Information for health care professionals: erythropoiesis stimulating agents. Updated 11/8/2007, <http://www.fda.gov/cder/drug/InfoSheets/HCP/RHE200711HCP.htm>

1c.16 Quote verbatim, the specific guideline recommendation (Including guideline # and/or page #):

1c.17 Clinical Practice Guideline Citation: KDOQI Clinical Practice Guideline and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease: 2007 Update of Hemoglobin Target, American Journal of Kidney Diseases, 50(3): Pages 471-530 (September 2007).

(2) KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Anemia in Chronic Kidney Disease, American Journal of Kidney Diseases, 49(Supplement 3): S1-S146, May 2006.

KDOQI Clinical Practice Guideline (CPG) and Recommendation (CPR): CPG AND CPR 3.2. USING IRON AGENTS

3.2.1 Frequency of iron status tests:

In the opinion of the Work Group, iron status tests should be performed as follows:

3.2.1.1 Every month during initial ESA treatment.

3.2.1.2 At least every 3 months during stable ESA treatment or in patients with HD-CKD not treated with an ESA.

1c.18 National Guideline Clearinghouse or other URL:

[http://www.kidney.org/professionals/KDOQI/guidelines\\_anemiaUP/guide1.htm](http://www.kidney.org/professionals/KDOQI/guidelines_anemiaUP/guide1.htm)

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: KDOQI members. No information on representation of disclosures regarding bias.

1c.21 System Used for Grading the Strength of Guideline Recommendation: [GRADE](#)

1c.22 If other, identify and describe the grading scale with definitions:

1c.23 Grade Assigned to the Recommendation: [A](#)

1c.24 Rationale for Using this Guideline Over Others: [No other guidelines are available.](#)

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?

1c.25 Quantity: [High](#) 1c.26 Quality: [High](#) 1c.27 Consistency: [High](#)

Was the threshold criterion, *Importance to Measure and Report*, met?

(1a & 1b must be rated moderate or high and 1c yes) Yes  No

Provide rationale based on specific subcriteria:

**For a new measure if the Committee votes NO, then STOP.**

**For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.**

## 2. RELIABILITY & VALIDITY - 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)

Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See [guidance on measure testing](#).

S.1 Measure Web Page (*In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? [Yes](#)

S.2 If yes, provide web page URL: [http://www.arborresearch.org/ESRD\\_QMA.aspx](http://www.arborresearch.org/ESRD_QMA.aspx)

2a. RELIABILITY. Precise Specifications and Reliability Testing: H  M  L  I

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement (*Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome*):

[Number of dialysis patients in the denominator 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, peritoneal dialysis patients, and home hemodialysis patients.](#)

2a1.2 Numerator Time Window (*The time period in which the target process, condition, event, or outcome is eligible for inclusion*):

[Data collected for this ESRD CPM are for the three-month time period \(Oct-Dec\) for the in-center hemodialysis patients, peritoneal dialysis, and home hemodialysis patients.](#)

2a1.3 Numerator Details (*All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*):

[Number of dialysis patients in the denominator 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, peritoneal dialysis patients, and home hemodialysis patients.](#)

2a1.4 Denominator Statement (*Brief, narrative description of the target population being measured*):

[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. The study period consists of 3 consecutive months for in-center hemodialysis patients, peritoneal dialysis patients and home hemodialysis. The hemoglobin value reported for the end of each](#)

study month (end-of-month Hb) is used for this calculation.

**2a1.5 Target Population Category** (Check all the populations for which the measure is specified and tested if any): **Adult/Elderly Care**

**2a1.6 Denominator Time Window** (The time period in which cases are eligible for inclusion):

Data collected for this ESRD CPM are for the three-month time period (Oct-Dec) for the in-center hemodialysis patients, peritoneal dialysis and home hemodialysis patients.

**2a1.7 Denominator Details** (All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

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. The study period consists of 3 consecutive months for in-center hemodialysis patients, peritoneal dialysis patients and home hemodialysis. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for this calculation.

**2a1.8 Denominator Exclusions** (Brief narrative description of exclusions from the target population):

Acute HD, transient dialysis patients (seen at the specific center for less than 30 days), and kidney transplant patients are excluded from the calculation this CPM.

**2a1.9 Denominator Exclusion Details** (All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses):

**2a1.10 Stratification Details/Variables** (All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses):

No stratification is required for this measure.

**2a1.11 Risk Adjustment Type** (Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13): **No risk adjustment or risk stratification**    **2a1.12 If "Other," please describe:**

**2a1.13 Statistical Risk Model and Variables** (Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.):

No risk adjustment necessary

**2a1.14-16 Detailed Risk Model Available at Web page URL** (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

**2a1.17-18. Type of Score:** **Rate/proportion**

**2a1.19 Interpretation of Score** (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score): **Better quality = Higher score**

**2a1.20 Calculation Algorithm/Measure Logic** (Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.):

**2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:**

<p>Attachment  <a href="#">2A CPM Calculation Flow chart.pdf</a></p>
<p><b>2a1.24 Sampling (Survey) Methodology.</b> 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):  <a href="#">N/A</a></p>
<p><b>2a1.25 Data Source</b> (<i>Check all the sources for which the measure is specified and tested</i>). If other, please describe:  <a href="#">Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</a></p>
<p><b>2a1.26 Data Source/Data Collection Instrument</b> (<i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): <a href="#">CROWNWeb</a></p>
<p><b>2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment:</b> <a href="#">URL</a>  <a href="http://www.projectcrownweb.org">http://www.projectcrownweb.org</a></p>
<p><b>2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:</b>  <a href="#">URL</a>  <a href="http://www.projectcrownweb.org">http://www.projectcrownweb.org</a></p>
<p><b>2a1.33 Level of Analysis</b> (<i>Check the levels of analysis for which the measure is specified and tested</i>): <a href="#">Facility</a></p>
<p><b>2a1.34-35 Care Setting</b> (<i>Check all the settings for which the measure is specified and tested</i>): <a href="#">Dialysis Facility</a></p>
<p><b>2a2. Reliability Testing.</b> (<i>Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.</i>)</p>
<p><b>2a2.1 Data/Sample</b> (<i>Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>):  <a href="#">CROWNWeb data from July 2009-December 2009 were analyzed. The number of facilities ranged from 3415-3453. The total number of patients per month ranged from 263,743 - 290,713.</a></p>
<p><b>2a2.2 Analytic Method</b> (<i>Describe method of reliability testing &amp; rationale</i>):  <a href="#">Reliability was assessed by calculating facility-level month-to-month correlations. Pearson correlation coefficients were calculated between the current performance month and previous month for reporting months August 2009 through October 2010.</a></p>
<p><b>2a2.3 Testing Results</b> (<i>Reliability statistics, assessment of adequacy in the context of norms for the test conducted</i>):  <a href="#">Reliability of this measure has improved over time. Correlation coefficients ranged from 0.42 to 0.73. The lowest correlation was observed in the second and third reporting months. In 2010, correlations from month-to-month were high (range: 0.53-0.73), thus indicating the data elements for this measure are reliable.</a></p>
<p><b>2b. VALIDITY. Validity, Testing, including all Threats to Validity:</b> H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/></p>
<p><b>2b1.1 Describe how the measure specifications</b> (<i>measure focus, target population, and exclusions</i>) <b>are consistent with the evidence cited in support of the measure focus</b> (<i>criterion 1c</i>) <b>and identify any differences from the evidence:</b>  <a href="#">The target population in the validity analysis was all ESRD patients on HD who are reported in CROWNWeb in 2009. The population and results from the validity analyses performed were consistent with the evidence provided. The validity analyses showed that relative to facilities with the highest percentage of assessment of iron stores, the Standardized Mortality Ratio (SMR) increased as assessment of iron stores decreased.</a></p>
<p><b>2b2. Validity Testing.</b> (<i>Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.</i>)</p>
<p><b>2b2.1 Data/Sample</b> (<i>Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included</i>):  <a href="#">2009 CROWNWeb data (July - December) were used to calculate monthly performance scores, and the SMR was calculated using</a></p>

2009 Medicare-paid dialysis claims and the Medical Evidence Form (Form CMS-2728). Documentation regarding the Medicare claims used to calculate the SMR is attached.

**2b2.2 Analytic Method** (*Describe method of validity testing and rationale; if face validity, describe systematic assessment*):  
 Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2009 SMR (methodology on SMR calculations is attached). Facility-level performance scores were divided into quintiles and the relative risk (RR) of mortality was calculated for each quintile. The highest quintile was used as the reference group. Thus, a RR>1.0 for the lower performance score quintiles would indicate a higher relative risk of mortality.

**2b2.3 Testing Results** (*Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment*):

Quintiles of the performance scores were defined as follows:

Q1:0-<94%

Q2:94%-<98%

Q3:98%-<99%

Q4:99%-<100%

Q5:100%-100%

Results from the Poisson model indicated lower performance scores were significantly associated with SMR ( $p<0.001$ ). Relative risks

of mortality was highest in the 2 lowest performance measure quintile (RR=1.08;95% CI: 1.04,1.11)and (RR=1.08;95% CI: 1.05,1.12). For quintiles 3 RR=1.03(95% CI:0.99,1.06) and was 1.05 for quintile 4 (95% CI:1.01,1.09).

These findings confirm the association between assessment of iron stores and improved mortality.

**POTENTIAL THREATS TO VALIDITY.** (*All potential threats to validity were appropriately tested with adequate results.*)

**2b3. Measure Exclusions.** (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

**2b3.1 Data/Sample for analysis of exclusions** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

CROWNWeb data from July through December 2009 included up to 3495 facilities per month with an average of 80 patients per facility. The total number of patients per month ranged from 267,515 - 290,713. The number of exclusions per month ranged from 40,383 - 61,911.

**2b3.2 Analytic Method** (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):

Exclusions were assessed by calculating and comparing final measures to the final measure among excluded patients. The calculations were done using all available Crownweb data.

**2b3.3 Results** (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses*):

The mean of assessment of iron stores for all patients was 96%(SD=0.09). The mean among exclusions was 14%(SD=0.15).

**2b4. Risk Adjustment Strategy.** (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

**2b4.1 Data/Sample** (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):

No risk adjustment is performed for this measure.

**2b4.2 Analytic Method** (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):

N/A

**2b4.3 Testing Results** (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot,*



and assessment of adequacy in the context of norms for risk models. *Risk stratification*: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):

N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: There is no evidence suggesting this measure should be risk adjusted.

**2b5. Identification of Meaningful Differences in Performance.** (The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.)

**2b5.1 Data/Sample** (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Analyses were performed using CROWNWeb data from January 2010. There were 3436 facilities and a total of 293,694 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

**2b5.2 Analytic Method** (Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance):

Facility-level percents of patients with Assessment of Iron Stores were calculated as the number of patients within the facility with serum ferritin concentration and percent transferrin saturation or reticulocyte Hb content are measured during the month divided by the total number of patients in the facility. The mean, SD, and quartiles also were calculated.

**2b5.3 Results** (Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningful differences in performance):

Analysis of CROWNWeb data from January 2010 indicated the mean percentage of patients with assessment of iron stores - HD & PD was 97% (SD=10%). Distribution: Min=0%, Max=100%, 1st quartile=97%, median=100%, 3rd quartile=100%.

**2b6. Comparability of Multiple Data Sources/Methods.** (If specified for more than one data source, the various approaches result in comparable scores.)

**2b6.1 Data/Sample** (Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included):

Multiple data sources were not used.

**2b6.2 Analytic Method** (Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure):

N/A

**2b6.3 Testing Results** (Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted):

N/A

**2c. Disparities in Care:** H  M  L  I  NA  (If applicable, the measure specifications allow identification of disparities.)

2c.1 If measure is stratified for disparities, provide stratified results (Scores by stratified categories/cohorts): This measure is not stratified.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:

No disparities have been identified.

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met? (Reliability and Validity must be rated moderate or high) Yes  No

Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

### 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)**

**C.1 Intended Purpose/ Use** (Check all the purposes and/or uses for which the measure is intended): [Public Reporting, Quality Improvement \(Internal to the specific organization\)](#), [Quality Improvement with Benchmarking \(external benchmarking to multiple organizations\)](#)

**3.1 Current Use** (Check all that apply; for any that are checked, provide the specific program information in the following questions): [Public Reporting](#)

**3a. Usefulness for Public Reporting:** H  M  L  I   
 (The measure is meaningful, understandable and useful for public reporting.)

**3a.1. Use in Public Reporting - disclosure of performance results to the public at large** (If used in a public reporting program, provide name of program(s), locations, Web page URL(s)). If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [**For Maintenance** – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.]

[Quality measure results will be evaluated for future public reporting on Medicare's Dialysis Facility Compare website.](#)

**3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting.** If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: [This measure has been reported in previous ESRD CPM Annual Reports. The report shows 97% of HD and 86% of PD patients with measurements of serum ferritin and TSAT during the study period. This measure allows the clear setting of targets that are actionable, easy to track, and in compliance with KDOQI guidelines.](#)

**3.2 Use for other Accountability Functions (payment, certification, accreditation).** If used in a public accountability program, provide name of program(s), locations, Web page URL(s): [N/A](#)

**3b. Usefulness for Quality Improvement:** H  M  L  I   
 (The measure is meaningful, understandable and useful for quality improvement.)

**3b.1. Use in QI.** If used in quality improvement program, provide name of program(s), locations, Web page URL(s): [**For Maintenance** – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement].

[This measure is not currently used in a quality improvement program. However, in previous years, this measure was reported in ESRD CPM Annual Reports. The ESRD CPM Project was a national effort designed to assist dialysis providers to improve patient care and outcomes.](#)

**3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement.** If usefulness was demonstrated (e.g., QI initiative), describe the data, method and results:  
[N/A](#)

Overall, to what extent was the criterion, *Usability*, met? H  M  L  I   
 Provide rationale based on specific subcriteria:

### 4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

**4a. Data Generated as a Byproduct of Care Processes:** H  M  L  I

<p>4a.1-2 How are the data elements needed to compute measure scores generated? <i>(Check all that apply)</i>.                  Data used in the measure are:                  generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition</p>
<p>4b. Electronic Sources: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/></p>
<p>4b.1 Are the data elements needed for the measure as specified available electronically <i>(Elements that are needed to compute measure scores are in defined, computer-readable fields)</i>: ALL data elements are in a combination of electronic sources</p> <p>4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:</p>
<p>4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/></p>
<p>4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:                  There are no potential barriers to retrieving data necessary for the measure, and there are no data availability issues.</p>
<p>4d. Data Collection Strategy/Implementation: H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/></p>
<p>A.2 Please check if either of the following apply <i>(regarding proprietary measures)</i>:                  4d.1 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 and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues <i>(e.g., fees for use of proprietary measures)</i>:                  The measurements of iron status are routinely (e.g. monthly) performed for patients on ESA therapy and are currently collected as part of CROWNWeb. Currently, around 60% of all dialysis facilities submit these data to CROWNWeb.</p>
<p>Overall, to what extent was the criterion, <i>Feasibility</i>, met? H <input type="checkbox"/> M <input type="checkbox"/> L <input type="checkbox"/> I <input type="checkbox"/>                  Provide rationale based on specific subcriteria:</p>

<b>OVERALL SUITABILITY FOR ENDORSEMENT</b>
<p>Does the measure meet all the NQF criteria for endorsement? Yes <input type="checkbox"/> No <input type="checkbox"/>                  Rationale:</p>
<p>If the Committee votes No, STOP.                  If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.</p>

<b>5. COMPARISON TO RELATED AND COMPETING MEASURES</b>
<p>If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.</p>
<p>5.1 If there are related measures <i>(either same measure focus or target population)</i> or competing measures <i>(both the same measure focus and same target population)</i>, list the NQF # and title of all related and/or competing measures:</p>
<p>5a. Harmonization</p>
<p>5a.1 If this measure has EITHER the same measure focus OR the same target population as <u>NQF-endorsed measure(s)</u>:                  Are the measure specifications completely harmonized?</p> <p>5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:</p>
<p>5b. Competing Measure(s)</p>

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible):

**CONTACT INFORMATION**

Co.1 Measure Steward (Intellectual Property Owner): [Centers for Medicare & Medicaid Services, 7500 Security Boulevard , Mail Stop S3-01-02, Baltimore, Maryland, 21244-1850](#)

Co.2 Point of Contact: [Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-](#)

Co.3 Measure Developer if different from Measure Steward: [Arbor Research/UM-KECC, 340 East Huron St. Suite 300, Ann Arbor, Michigan, 48104](#)

Co.4 Point of Contact: [Claudia, Dahlerus, Claudia.Dahlerus@arborresearch.org, 734-665-4108-](#)

Co.5 Submitter: [Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-](#), [Centers for Medicare & Medicaid Services](#)

Co.6 Additional organizations that sponsored/participated in measure development:

Co.7 Public Contact: [ESRD Quality Measures, Help Desk, ESRD\\_quality\\_measures@arborresearch.org, 877-665-1680-](#), [Arbor Research Collaborative for Health](#)

**ADDITIONAL INFORMATION**

Workgroup/Expert Panel involved in measure development

Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: [No changes to this measure title are requested](#)

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.3 Year the measure was first released: [2007](#)

Ad.4 Month and Year of most recent revision: [11, 2007](#)

Ad.5 What is your frequency for review/update of this measure? [Every 3 years](#)

Ad.6 When is the next scheduled review/update for this measure? [06, 2013](#)

Ad.7 Copyright statement/disclaimers:

Ad.8 Additional Information/Comments:

Date of Submission (MM/DD/YY): [06/23/2011](#)

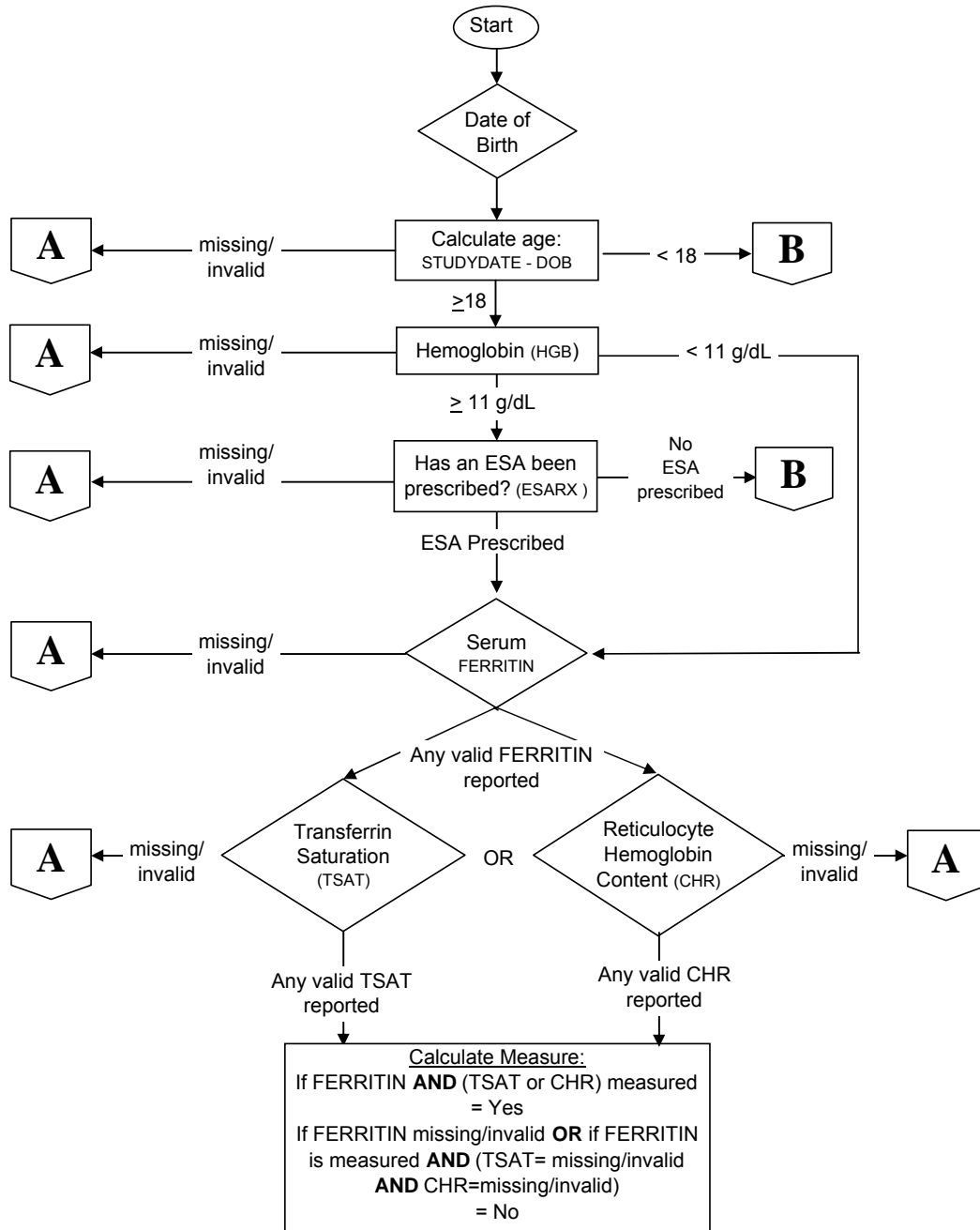
**Anemia Management**

**CPM IIa: Assessment of Iron Stores**

**Numerator:** Adult HD or PD patients with assessment of iron stores in at least once during the 3-month study period to include serum ferritin (FERRITIN) and transferrin saturation (TSAT) or reticulocyte hemoglobin content (CHR).

**Denominator:** All adult ( $\geq 18$  years old) HD or PD patients where hemoglobin (HGB) is  $< 11.0$  g/dL (110 g/L) for at least one of the study measurement periods or if an ESA is prescribed (ESARX=1) at any of the three study measurement periods, regardless of hemoglobin.

**Exclusions:** Transient dialysis patients ( $< 30$  days at this center), kidney transplant patients, acute HD. Patients not prescribed an ESA who have HGB  $\geq 11$ . Pediatric patients.



**A** Excluded due to missing/invalid data

**B** Exclude for failing to meet inclusion criteria