

DRAFT

Anemia of chronic kidney disease: ESA management to avoid transfusion

3b Measure Justification

Importance

- ◆ **High Impact Aspect of Health Care**

- **Demonstrated high impact aspect**

1a1.1 Select from the following all that apply:

- *Affects large numbers*
- *A leading cause of morbidity/mortality*
- *Frequently performed procedure*
- *High resource use*
- *Patient/societal consequences of poor quality*

During 2011, ESA use for treatment of anemia in dialysis patients is ubiquitous and 40% of ESA-treated patients had average achieved hemoglobin (hgb) levels below 11 g/dl. Changes in financial incentives for providing ESAs for treatment of anemia following the implementation of the prospective payment system and changes in the FDA recommendations on ESA use, have given rise to concerns that patients with low hemoglobin may be denied access to ESAs in favor of red blood cell transfusion. Several studies have detected an increase in transfusion rates in dialysis patients in recent months. It has also been postulated that a national trend toward increased use of transfusions in dialysis patients would adversely affect the supply of blood available for acute injuries and surgical procedures. Lastly, greater exposure to human leukocyte antigens, present in transfused blood, may increase anti-HLA antibodies in kidney transplant candidates, resulting in reduced access to kidney transplantation. The proposed measure would be used to monitor facility rates of transfusion use among patients with low hgb and low ESA dose who are not already considered high risk for transfusion. Shifts in national practice patterns from use of ESAs to use of transfusion would be reported to CMS for evaluation.

- **Summary of evidence of high impact**

1a3. Provide epidemiological or resource use data

Ibrahim et al. evaluated trends in red blood cell transfusion in dialysis patients in 2008 in response to concerns that increases in transfusion rates would negatively impact dialysis patient care. Hollenbeak (2012) addressed the possibility that increased demand for transfusions would negatively impact the national blood supply. The United States Renal Data System (USRDS) identifies an increase in transfusion rates in 2011 compared to 2010 (USRDS ADR Figure 10.10). While 2010 had lower transfusion rates than prior years, the potential for increased transfusion rates lead Liu et al. to begin to develop a facility-level transfusion metric in 2012.

Unpublished analyses by Arbor Research and KECC have shown meaningful variation in facility level practice with regard to transfusions, leading to the development of several measures for monitoring and evaluation of transfusion rates.

- **Citations**

1a.4. Provide citations for the evidence described above

- Ibrahim HN, et al. Temporal Trends in red blood transfusion among US dialysis patients, 1992-2005. Am J Kidney Dis 2008; 52: 1115
- Hollenbeak et. al. *The Impact of End-Stage Renal Disease Transfusion Demand on Blood Utilization and Blood Supply in the United States* Health Outcomes Research in Medicine Volume 3, Issue 2, May 2012, Pages e67–e77
- USRDS 2012 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2012.
- Liu et al. Development of a Facility-Level Transfusion Quality of Care Metric, 2012 American Society of Nephrology Annual Kidney Week
- FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease.
<http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>
- Highlights of prescribing information: Epogen (epoetin alfa)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103234Orig1s5166_103234Orig1s5266lbl.pdf
- Highlights of prescribing information: Aranesp (darbepoetin alfa)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103951Orig1s5173_103951Orig1s5258lbl.pdf
- Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279–335.

Opportunity for Improvement

- **Briefly explain the benefits envisioned by use of this measure**

1b.1. (Quality improvement anticipated)

This measure is intended to guard against decline in access to optimal care for dialysis patients by monitoring shifts in resource utilization/treatment from ESA use to dependence on transfusions. Changes in economic incentives of EPO dose and well documented guidelines about risks associated with excessive ESA dose may result in more frequent resource intensive red blood cell transfusions and thereby poorer anemia management and lower quality of life for patients. The proposed measure would be used to monitor transfusion rate and that may help to control escalating medical costs and avoid underuse of ESAs.

- **Summary of data demonstrating performance gap**

1b.2. (Variation or overall less than optimal performance across providers)

In the test calculation of the measure using 2011 claims data, the facility-level mean was 4.8 per 1,000 patient-months (SD=19.5). The median, 25th, and 75th percentiles were 1.7, 0.0, and 5.7 per 1,000 patient-months, respectively. The table below shows the distribution of scores for each of four years, 2008-2011.

Year	# Facilities	Mean	std	Min	25th	50th	75th	Max
2008	5123	3.5	23.5	0.0	0.0	0.0	3.7	1000.0
2009	5408	3.2	18.7	0.0	0.0	0.0	3.4	1000.0
2010	5561	3.4	21.7	0.0	0.0	0.0	3.5	1000.0
2011	5697	4.8	19.5	0.0	0.0	1.7	5.7	1000.0

○ **Citations**

1b.3. Provide citations for the evidence described above

- Unpublished analysis on draft ESA management to avoid transfusion measure based on Medicare claims done by Arbor Research Collaborative for Health and Kidney Epidemiology and Cost Center- University of Michigan.

○ **Summary of data on disparities by population group**

1b.4. Summarize evidence found that demonstrates any disparities. Describe groups in which disparities exist.

Investigations of the STrR by race, sex and ethnicity groups indicate relatively little variation and no substantial disparities among these groups. Although females are somewhat more likely to receive transfusions than males, analyses showed that a model with race and sex included and a model without these variables yielded very similar results for the facility STrR measure as well as for the parameter estimates for other variables. The table below shows the parameter estimates for the race, sex and ethnicity variables based on a model that included these variables along with other covariates.

Model with sex, race, ethnicity included along with other covariates			
Parameter	Estimate	Standard Error	P value
Females	0.05237	0.00894	<.0001
Native American*	-0.1493	0.02248	<.0001
Asian*	-0.25304	0.01368	<.0001
Black*	-0.11121	0.00612	<.0001
Other Race*	-0.10109	0.02499	<.0001
Hispanic ¥	-0.20432	0.00852	<.0001

*White used as reference

¥Non-Hispanic used as reference

- **Citations**

1b.5. Provide citations for the evidence described above

Unpublished analysis by Arbor Research Collaborative for Health and Kidney Epidemiology and Cost Center-University of Michigan, submitted to CMS.

- ◆ **Evidence to Support Measure Focus**

- **Structure-process-outcome relationship**

1c.1. Briefly state the measure focus (for example, health outcome, intermediate clinical outcome, process, structure) Then, identify the appropriate links (for example, structure-process-health outcome, process-health outcome, intermediate clinical outcome-health outcome)

While this is a process measure addressing facility anemia management practices, the measure focuses on transfusions as the undesirable result of lack of ESA treatment. Change in economic incentives of EPO use may lead to more frequent use of transfusions to treat anemia, which may result in poorer anemia management and lower quality of life for patients. FDA guidelines suggest using the lowest dose of ESAs needed to avoid transfusions. Limiting the numerator to patients with low hgb and low ESA dose, while excluding patients with high risk of transfusion, focuses the measure on transfusions that could have been avoided.

Type of evidence

- *1c.2. Describe the type of evidence, selecting from the following list all that apply: Clinical practice guideline*
- *Selected individual studies (rather than entire body of evidence)*
- *Systematic review of body of evidence (other than within guideline development)*
- *Other (state type of evidence)*

Evidence comes from clinical practice guidelines and selected individual studies.

- **Directness of evidence to the specified measure**

1c.4. 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 current body of evidence has CKD patients that are both on and not on dialysis, whereas the target population for this measure is restricted to CKD patients on dialysis. Most studies have focused on different hemoglobin targets with regards to cardiovascular and quality of life endpoints and have not specifically addressed ESA dosing strategies to avoid transfusion, which was the focus of the original ESA research.

- **Quantity of studies in the body of evidence**

1c.5. Total number of studies, not articles

In addition to the KDIGO Guidelines and the FDA guidance, the measure developer and technical expert panel reviewed a comprehensive set of 31 articles on transfusion in dialysis patients published during 1990-2011.

- **Quality of body of evidence**

1c.6. 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 (for example, interventions, comparisons, outcomes assessed, population included in the evidence)*
Imprecision/wide confidence intervals due to few patients or events)

The relevant KDIGO Guideline was given a “moderate” grade for quality of evidence.

- **Consistency of results across studies**

1c7. Summarize the consistency of the magnitude and direction of the effect across studies

The majority of the reviewed studies agreed transfusions should be avoided when possible.

- **Net benefit**

1c8. Provide estimates of effect for benefit/outcome, identify harms addressed and estimates of effect, and net benefit---benefit over harms across studies. Please include results of business/social/economic case for the measure.

Hollenbeak et al. suggested that increased transfusions among dialysis patients would impact the availability of blood nationally. The effects of transfusion compared to ESA use are well established leading the FDA to recommend use of ESAs to avoid transfusion.

- **Grading of strength/quality of the body of evidence**

1c9, 1c10, 1c11, 1c13, 1c14. Please address:

- *Indicate if the body of evidence has been graded*
- *If the body of evidence was graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias*
- *System used for grading the body of evidence*
- *Grade assigned to the body of evidence*
- *Summary of controversy/contradictory evidence*

N/A: Transfusion avoidance is an outcome measure.

- **Citation**

1c15. Provide citations for the evidence described above

- Besarab A, Bolton WK, Browne JK, et al. "The effects of normal as compared with low hematocrit values in patients with cardiac disease who are receiving hemodialysis and epoetin." The New England journal of medicine (1998) 339:584-90. PMID: 9718377
- Singh AK, Szczec L, Tang KL, et al. "Correction of anemia with epoetin alfa in chronic kidney disease." The New England journal of medicine (2006) 355:2085-98. PMID: 17108343
- Drüeke TB, Locatelli F, Clyne N, et al. "Normalization of hemoglobin level in patients with chronic kidney disease and anemia." The New England journal of medicine (2006) 355:2071-84. PMID: 17108342

- Pfeffer MA, Burdmann EA, Chen CY, et al. "A trial of darbepoetin alfa in type 2 diabetes and chronic kidney disease." The New England journal of medicine (2009) 361:2019-32. PMID: 19880844

◦ **Guideline recommendation**

1c16. Quote verbatim, the specific guideline recommendation (Including guideline number and/or page number)

- KDIGO Anemia Guidelines 2012: Guideline 3.2: In initiating and maintaining ESA therapy, we recommend balancing the potential benefits of reducing blood transfusions and anemia-related symptoms against the risks of harm in individual patients (e.g., stroke, vascular access loss, hypertension). (1B).
- KDIGO Anemia Guidelines 2012: Guideline 4.1.1: When managing chronic anemia, we recommend avoiding, when possible, red cell transfusions to minimize the general risks related to their use. (1B)
- KDIGO Anemia Guidelines 2012: Guideline 4.1.3: When managing chronic anemia, we suggest that the benefits of red cell transfusions may outweigh the risks in patients in whom (2C):
 - ESA therapy is ineffective (e.g., hemoglobinopathies, bone marrow failure, ESA resistance)
 - The risks of ESA therapy may outweigh its benefits (e.g., previous or current malignancy, previous stroke)
- FDA guideline to use minimum amount of ESAs to avoid transfusion.

◦ **Citation**

1c17. Provide citations for the clinical practice guideline quoted above

- FDA Drug Safety Communication: Modified dosing recommendations to improve the safe use of Erythropoiesis-Stimulating Agents (ESAs) in chronic kidney disease.
<http://www.fda.gov/Drugs/DrugSafety/ucm259639.htm>
- Highlights of prescribing information: Epogen (epoetin alfa)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103234Orig1s5166_103234Orig1s5266lbl.pdf
- Highlights of prescribing information: Aranesp (darbepoetin alfa)
http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/103951Orig1s5173_103951Orig1s5258lbl.pdf
- Kidney Disease: Improving Global Outcomes (KDIGO) Anemia Work Group. KDIGO Clinical Practice Guideline for Anemia in Chronic Kidney Disease. Kidney inter., Suppl. 2012; 2: 279–335.

◦ **URL**

1c18. National Guideline Clearinghouse or other URL

http://www.kdigo.org/clinical_practice_guidelines/pdf/KDIGO-Anemia%20GL.pdf

◦ **Grading of strength of recommendation**

1c19 1c21, 1c23. Please address:

- *Has the recommendation been graded? Yes*
- *System used for grading the strength of guideline recommendation (USPSTF, GRADE, etc.) Grade assigned to the recommendation*

The KDIGO Guidelines used the GRADE system: (1- We recommend, 2- We suggest) combined with a 4 category quality of evidence grading (A, B, C, D). The grades given are listed above with the relevant guidelines.

FDA recommendations resulted from internal review of published and unpublished data submitted to FDA

- **Rationale for using this guideline over others**

1c24. If multiple guidelines exist, describe why the guideline cited was chosen. Factors may include rigor of guideline development, widespread acceptance and use, etc.

KDIGO Clinical Practice Guidelines for Anemia in Chronic Kidney Disease are the most recently published guidelines. In addition, they were developed by an international consortium of dialysis organizations using rigorous literature review and systematic grading methodology

- **Overall assessment of the body of evidence**

1c25, 1c26, 1c.27. Based on the NQF descriptions for rating the evidence, what was your assessment of the following attributes of the body of evidence?

- Quantity
- Quality
- Consistency

The Guidelines used to support this measure development were graded 1B and 2C. The guideline to use ESAs with caution and to balance the risks against benefits is strongly supported by evidence from both clinical and observational trials, some of which are cited above. KDIGO evaluators rated the strength of this recommendation as “1B”, supporting our belief that the measure submitted is well supported by the available evidence.

Reliability and Validity – Scientific Acceptability of Measure Properties

- ◆ **Reliability Testing**

- **Data sample**

2a2.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Reliability of the measure was assessed using data on ESRD patients over a four year period of 2008-2011. Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

- **Analytic methods**

2b2.2 .Describe method of validity testing and rationale; if face validity, describe systematic assessment

To assess reliability, we assessed the degree to which the measure was consistent year to year. If one looks at two adjacent time intervals, one should expect that a reliable measure will exhibit correlation over these periods since large changes in patterns affecting the measure should not occur for most centers over shorter periods. Year to year variability in the measure values was assessed across the years 2008, 2009, 2010 and 2011 based on dialysis centers with more than 10 patients represented in the denominator and for which a 2012 Dialysis Facility Report (DFR) is available.

- **Testing results**

2a2.3. Provide reliability statistics and assessment of adequacy in the context of norms for the test conducted

The practice identified by this measure has been historically rare and is persistent in relatively few facilities. However, it will be useful to monitor potential increases in this practice. The Spearman's rank correlation between the rates across adjacent years (2008 vs. 2009, 2009 vs. 2010, and 2010 vs. 2011) was consistently 0.23, indicating a tendency for facilities with higher or lower transfusion rates in one year to have higher or lower transfusion rates in the following year. . These correlations were significant, based on a large sample size. A total of 2,729 (46%) of the 5991 facilities nationally had more than one year with a positive value. Just over half of facilities (54%) had either no values (27%) or one value (27%) during the four year period. A total of 1,394 facilities had more than two positive values over the four year period. The measure is based on complete data and is not subject to judgment or rater variability. Hence the measures of inter-rater variability are not relevant here.

- ◆ **Validity Testing**

- **Data sample**

2b2.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

N/A

- **Analytic method**

2b2.2 .Describe method of validity testing and rationale; if face validity, describe systematic assessment

N/A

- **Testing results**

2b2.3. (Provide statistical results and assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)

Face validity of the measure was established during the CMS Technical Expert Meeting held in May 2012 during which an overwhelming majority of participants were in favor of developing a measure that monitored transfusion events in this population.

- ◆ **Exclusions**

- **Data sample for analysis of exclusions**

2b3.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Comorbidity exclusions of the measure were assessed using data on ESRD patients for 2011. These data represent 1,779,435 patient-months, and 27,196 transfusions at 5,697 facilities. These data are part of an extensive national ESRD patient database, which we derive from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS

Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

- **Analytic method**

2b3.2. Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference

Patients are excluded if they have a documented history of hemoglobinopathy, acquired or hereditary hemolytic anemia, aplastic anemia, myelodysplasia, myeloma, myelofibrosis, or cancer, as these comorbidities are associated with higher risk of transfusion and require different anemia management practices that the measure is not intended to address. The increased risk of transfusion for patients with these comorbidities was assessed by fitting univariate logistic regression models of one or more RBC transfusions based on groups of comorbidities.

Patient-months are excluded from the measure if on the first of the month the patient is fewer than 90 days since first ESRD service date due to incompleteness of data and differing ESA dose practices. In addition, patients that are less than 18 years of age are excluded due to the relatively small number of pediatric patients treated at most facilities. To ensure quality in the calculation of ESA dose per session per kg, patient-months are excluded if a patient was treated for fewer than six sessions at a particular facility, or if the patient switched type of ESA during the month.

- **Results**

2b3.3. Provide statistical results for analysis of exclusions (for example, frequency, variability, sensitivity analyses)

A total of 38.78% of patients were excluded from the initial cohort due to the comorbidity exclusions. A patient can be excluded due to multiple comorbidities.

Comorbidity exclusions were assessed using univariate logistic regression models of one or more RBC transfusion events in a month based on each category of comorbidities for the year 2011. Each of the comorbidities was a significant predictor of RBC transfusion events with odds ratios ranging from 1.46 to over 4.

- ◆ **Risk Adjustment Strategy**

- **Rationale for no adjustment**

2b4.4. If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment. The three rows above may be deleted if this field is used. Delete row if measure is risk adjusted or if this is a process measure.

Patients with the above comorbidities that are associated with a higher risk of transfusion, and for whom typical ESA dosing practices may differ from the FDA guidelines, were excluded from the measure. The rationale for excluding these patients rather than adjusting for their underlying conditions is that the measure is intended to capture the dialysis facility's anemia management process of care, which may be obscured by inclusion of patients for whom the risk of transfusion is beyond the facility's control. The recent Technical Expert Panel (TEP) recommended exclusion of patients who may be unresponsive to ESA treatment, or may experience side effects of

ESA treatment due to comorbid conditions, or patients for whom the responsibility of anemia management falls on multiple care providers.

◆ **Identification of Meaningful Differences in Performance**

○ **Data/ sample**

2b5.1 Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

Meaningful differences in performance of the measure were assessed using data on ESRD patients over a four year period of 2008-2011. Data for the measure are derived from an extensive national ESRD patient database, which is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The database is comprehensive for Medicare patients.

○ **Analytic method**

2b5.2. Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance

The distribution of the measure in 2011 was examined between facilities grouped into quartiles of average achieved hemoglobin (obtained from the 2012 DFR), and percent of patients with average achieved hemoglobin less than 10 g/dL (obtained from the 2012 DFR). In addition, due to the measure's focus on monitoring for potential shifts, we examine the distribution of the measure from 2008 through 2011.

○ **Testing results**

2b5.3. Results-Provide measure performance results/scores (for example, distribution by quartile, mean, median, SD, etc.); identification of statistically significant and meaningfully differences in performance

The distribution of the measure shrinks towards zero as the average achieved hemoglobin increases. The 2011 25th percentile, median and 75th measure percentile for facilities with an average achieved hemoglobin less than 10.85 g/dL was 0.0, 3.8 and 8.7 per 1,000 patient-months. For facilities in the upper quartile, with average achieved hemoglobin of greater than 11.20 g/dL, the 25th percentile, median and 75th percentile was 0.0, 0.0, and 3.8 per 1,000 patient-months.

Distribution of Measure Scores by Quartile of Average Achieved Hemoglobin, 2011

Hgb Quartile	# Facilities	Mean	25th	50th	75th
< 10.85	1388	7.0	0.0	3.8	8.7
10.85 - 11.02	1388	4.1	0.0	2.5	5.9
11.03 - 11.20	1388	3.1	0.0	0.7	4.8
> 11.20	1388	2.8	0.0	0.0	3.8

The distribution of the measure shrinks towards zero as the percent of patients with an achieved hemoglobin less than 10 g/dL decreases. The 2011 25th percentile, median and 75th measure percentile for facilities with less than 1.23% of patients having an average achieved hemoglobin less than 10 g/dL was 0.0, 0.0 and 4.46 per 1,000 patient-months. For facilities in the upper quartile, with more than 6.89% of patients with an average achieved hemoglobin less than 10 g/dL, the 25th percentile, median and 75th percentile was 0.0, 3.88, and 8.30 per 1,000 patient-months.

Distribution of Measure Scores by Quartile of Percent of Patients w/ Hemoglobin < 10, 2011

Hgb < 10					
Quartile	# Facilities	Mean	25th	50th	75th
< 1.25	1318	3.05	0	0	4.46
1.25 - 3.77	1313	3.25	0	2.18	4.88
3.78 - 6.89	1315	3.55	0	2.25	5.41
> 6.89	1334	5.85	0	3.88	8.30

The distribution of the measure values by year is shown in 1b.2.

◆ **Comparability of Multiple Data Sources/Methods**

○ **Data/ sample**

2b6.1. Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included

N/A

○ **Analytic method**

2b6.2. Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure

N/A

○ **Testing results**

2b6.3. Provide statistical results (for example, correlation statistics, comparison of rankings) and assessment of adequacy in the context of norms for the test conducted

N/A

◆ **Disparities in Care**

○ **Stratification**

2c.1. If measure is stratified for disparities, provide stratified results (scores by stratified categories/cohorts)

N/A

○ **Rationale for no stratification**

2c.2. If disparities have been reported/identified, but measure is not specified to detect disparities, please explain.

Patients for whom ESA dosing practices differ from the FDA guidelines, used as a model for this measure, were excluded from the measure. Therefore it was not necessary to stratify the measure.

- **Supplemental information**

2.1. Supplemental testing methodology information: If additional information is available, please indicate where this information can be found: appendix, attachment, or URL

N/A

Usability

- ◆ **Public Reporting**

- **Meaningful, understandable and useful**

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, for example, within 3 years of endorsement)

This measure may be included on <http://www.medicare.gov/> Dialysis Facility Compare website in the future.

3a.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (for example, focus, group, cognitive testing) describe the data, method and results.

CMS has scheduled the measure to undergo public comment in early 2013, after which CMS will submit the measure for NQF approval. Once the measure has undergone the NQF review process, we plan to include the measure in the publicly available Dialysis Facility Reports.

This measure is modeled specifically from the FDA guidance for use of ESAs. Therefore the measure results can act as a useful monitoring tool for facilities' successful adherence to the guidelines. Potential reporting of the measure in future releases of the Dialysis Facility Reports or Dialysis Facility Compare could provide stakeholders an opportunity to monitor the measure and compare their results to other facilities at the national and regional levels.

- ◆ **Quality Improvement**

- **Meaningful, understandable and useful**

3b.1. Use in QI (If used in quality improvement program, provide name of program(s), locations, Web page URL(s))

3b.2. Provide a rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated (for example, QI, initiative) describe the data, method and results

This measure is modeled specifically from the FDA guidance for use of ESAs. Therefore the measure results can act as a useful monitoring tool for facilities' successful adherence to the guidelines. Facilities that observe increases of the measure over time may be able to identify improvement needs in their anemia management practices.

◦ **Other accountability uses**

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)). This row may be deleted if not applicable.

N/A

Feasibility

◆ **How the data elements needed to compute measure score are generated**

4a.1. How are the data elements needed to compute measure scores generated? State all that apply. Data used in the measure are:

Data used in the measure are obtained from Medicare claims generated by and used by health care personnel during the provision of care, i.e. lab values, medical conditions and claims data.

◆ **Electronic availability**

4b.1. Are the data elements needed for the measure as specified available electronically (elements that are needed to compute measure scores are in defined, computer-readable fields)?

ALL data elements in electronic claims

◆ **Susceptibility to inaccuracies, errors, or unintended consequences**

4c.1. Identify susceptibility to inaccuracies, errors, or unintended consequences of measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results.

Some lag in transfusion count obtained from hospital claims is expected. If the data are measured too early, the counts may be artificially low. Aside from transfusion data lag, there are no barriers to retrieving the data necessary for the measure, and there are no data availability issues. Burden is minimal as no incremental data collection is needed.

Data collection strategy

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 (for example fees for use of proprietary measures)

The data are from Medicare (A and B) institutional claims.

Related Measures

◆ **Harmonization**

5a.1. If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? If so, describe.

N/A

◆ **Similar measures**

5b.1. If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s) or other measures in current use, describe why this measure is superior to existing measures (for example, a more valid or efficient way to measure quality); OR, provide a rationale for the additive value of developing and endorsing an additional measure. (Provide analyses when possible.)

This measure focuses on ensuring that dialysis patients' anemia is properly managed and that patients are not undertreated. This is a similar focus to the measure of the percent of patients with hemoglobin less than 10 g/dL, that has previously been used in the ESRD Quality Incentive Program, reported on Dialysis Facility Compare, and is currently reported in the Dialysis Facility Reports. This new measure is modeled specifically from the guidance of the FDA, and does not rely on assessment of an outcome threshold that lacks clinical trial based evidence.

DRAFT