



## Measure Information

This document contains the information submitted by measure developers/stewards, but is organized according to NQF's measure evaluation criteria and process. The item numbers refer to those in the submission form but may be in a slightly different order here. In general, the item numbers also reference the related criteria (e.g., item 1b.1 relates to subcriterion 1b).

### Brief Measure Information

**NQF #: 2699**

**De.2. Measure Title:** Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio (STrR)

**Co.1.1. Measure Steward:** Centers for Medicare & Medicaid Services

**De.3. Brief Description of Measure:** The risk adjusted facility level transfusion ratio "STrR" is specified for all adult dialysis patients. It is a ratio of number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusions that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

**1b.1. Developer Rationale:** Several changes in the ESRD system are likely to impact anemia management. These include identification of safety concerns associated with aggressive erythropoiesis-stimulating agent (ESA) use, expansion of the ESRD Prospective Payment System bundled payment, and the development of the ESRD Quality Incentive Program. There are concerns that these changes could result in underutilization of ESAs, with lower achieved hemoglobin values that may increase the frequency of red blood cell transfusion in the US chronic dialysis population.

Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g. ESA, iron). In addition, dialysis patients who are eligible for kidney transplant and are transfused risk the development of becoming sensitized to the donor pool thereby making transplant more difficult to accomplish. Blood transfusions carry a small risk of transmitting blood borne infections, development of a transfusion reaction, and using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.

Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to a national standard, allows for detection of treatment patterns in dialysis-related anemia management. This is of particular importance due to recent FDA guidance regarding minimizing the use of ESAs and new economic incentives to minimize ESA use introduced by Medicare bundling payment for ESAs. As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment it becomes more important to monitor for an overreliance on transfusions.

**S.4. Numerator Statement:** Number of eligible observed red blood cell transfusion events. Events are defined as transfer of one or more units of blood or blood products into recipient's blood stream (code set is provided in the numerator details) among patients dialyzing at the facility during the inclusion episodes of the reporting period. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

**S.7. Denominator Statement:** Number of eligible red blood cell transfusion events (as defined in the numerator statement) that would be expected among patients at a facility during the reporting period, given the patient mix at the facility. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

**S.10. Denominator Exclusions:** All transfusions associated with transplant hospitalization are excluded. Patients are excluded if they have a Medicare claim for hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, and sickle cell anemia within one year of their patient at risk time. Since these comorbidities are associated with higher risk of transfusion and require different anemia management practices that the measure is not intended to address, every patient's risk window is modified to have at least 1 year free of claims that contain diagnoses on the exclusion list.

**De.1. Measure Type:** Outcome  
**S.23. Data Source:** Administrative claims, Electronic Clinical Data  
**S.26. Level of Analysis:** Facility

**IF Endorsement Maintenance – Original Endorsement Date: Most Recent Endorsement Date:**

**IF this measure is included in a composite, NQF Composite#/title:**

**IF this measure is paired/grouped, NQF#/title:**

**De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results?** N/A

## 1. Evidence, Performance Gap, Priority – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. ***Measures must be judged to meet all subcriteria to pass this criterion and be evaluated against the remaining criteria.***

**1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form**  
[STrR\\_NQF\\_Evidence.docx](#)

### 1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- disparities in care across population groups.

**1b.1. Briefly explain the rationale for this measure** (e.g., the benefits or improvements in quality envisioned by use of this measure)  
Several changes in the ESRD system are likely to impact anemia management. These include identification of safety concerns associated with aggressive erythropoiesis-stimulating agent (ESA) use, expansion of the ESRD Prospective Payment System bundled payment, and the development of the ESRD Quality Incentive Program. There are concerns that these changes could result in underutilization of ESAs, with lower achieved hemoglobin values that may increase the frequency of red blood cell transfusion in the US chronic dialysis population.

Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g. ESA, iron). In addition, dialysis patients who are eligible for kidney transplant and are transfused risk the development of becoming sensitized to the donor pool thereby making transplant more difficult to accomplish. Blood transfusions carry a small risk of transmitting blood borne infections, development of a transfusion reaction, and using infusion centers or hospitals to transfuse patients is expensive, inconvenient, and could compromise future vascular access.

Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to a national standard, allows for detection of treatment patterns in dialysis-related anemia management. This is of particular importance due to recent FDA guidance regarding minimizing the use of ESAs and new economic incentives to minimize ESA use introduced by Medicare bundling payment for ESAs. As providers use less ESAs in an effort to minimize the risks associated with aggressive anemia treatment it becomes more important to monitor for an overreliance on transfusions.

**1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis.** (This is required for endorsement maintenance. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included). This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.

The STrR is a facility-level measure, comparing the observed number of red blood cell transfusions counts at a facility with the number of transfusions that would be expected under a national norm, after accounting for the patient characteristics within each facility. Standardized transfusion ratios vary across facilities. The data below shows the distribution of STrR using Medicare claims data for 2009-2012. This data is displayed in a tabular format in the appendix.

2009: 5478 facilities, 1.060 mean STrR, 1.384 Standard Error. Facility percentiles: 0.380 (10th), 0.626 (25th), 0.911 (50th), 1.256 (75th), 1.713 (90th).

2010: 5655 facilities, 1.031 mean STrR, 0.952 Standard Error. Facility percentiles: 0.370 (10th), 0.605(25th), 0.898 (50th), 1.272 (75th), 1.741(90th).

2011: 5793 facilities, 1.058 mean STrR, 1.672 Standard Error. Facility percentiles: 0.368 (10th), 0.622(25th), 0.915(50th), 1.297(75th), 1.741(90th)

2012: 5899 facilities, 1.045 mean STrR, 0.765 Standard Error. Facility percentiles: 0.398(10th), 0.635(25th), 0.913(50th), 1.287(75th), 1.760(90th)

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 (Form CMS-2744), Medicare dialysis and hospital payment records, the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746), the Nursing Home Minimum Dataset, and the Social Security Death Master File. The database is comprehensive for Medicare patients. Information on transfusions is obtained from Medicare Inpatient and Outpatient Claims Standard Analysis Files (SAFs).

The data below shows the number of facilities, patients, total count of transfusions and total patient years at risk for each year. Also, we calculate unadjusted or raw transfusion rates per year (defined as total transfusions divided by total patient years at risk). This data is displayed in a tabular format in the appendix.

2009: 5478 facilities, 377957 patients, 92767 total transfusions, 215069.1 total patient years at risk, 43.13 raw transfusion rate per 100 patient years at risk\*.

2010: 5655 facilities, 395183 patients, 93520 total transfusions, 223699.0 total patient years at risk, 41.80 raw transfusion rate per 100 patient years at risk\*.

2011: 5793 facilities, 405104 patients, 102547 total transfusions, 227598.8 total patient years at risk, 45.06 raw transfusion rate per 100 patient years at risk\*.

2012: 5899 facilities, 424563 patients, 108126 total transfusions, 233794.9 total patient years at risk, 46.25 raw transfusion rate per 100 patient years at risk\*.

\*This analysis includes all facilities for the given year.

**1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.**

N/A

**1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (This is required for endorsement maintenance. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the subcriterion on improvement (4b.1) under Usability and Use.**

Analyses of the STrR by race, sex and ethnicity indicate relatively little variation and no disparities substantial to the measure among these groups. Although females are somewhat more likely to receive transfusions than males, analyses showed that a model with variables for 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 data below shows the parameter estimates for the race, sex and ethnicity variables based on a model that included these variables along with other covariates. This data is displayed in a tabular format in the appendix.

Females: 0.1276 estimate, 0.0033 standard error, <.0001 p-value.  
Native American\*: -0.1409 estimate, 0.0175 standard error, <.0001 p-value.  
Asian\*: -0.2457 estimate, 0.0103 standard error, <.0001 p-value  
Black\*: -0.0924 estimate, 0.0045 standard error, <.0001 p-value  
Other Race\*: -0.0202 estimate, 0.0190 standard error, 0.2879 p-value  
Hispanic #: -0.1945 estimate, 0.0064 standard error, <.0001 p-value

\*White as reference

# Non-Hispanic as reference

**1b.5. If no or limited data on disparities from the measure as specified is reported in 1b4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations.**

N/A

**1c. High Priority** (previously referred to as High Impact)

The measure addresses:

- a specific national health goal/priority identified by DHHS or the National Priorities Partnership convened by NQF; OR
- a demonstrated high-priority (high-impact) aspect of healthcare (e.g., affects large numbers of patients and/or has a substantial impact for a smaller population; leading cause of morbidity/mortality; high resource use (current and/or future); severity of illness; and severity of patient/societal consequences of poor quality).

**1c.1. Demonstrated high priority aspect of healthcare**

High resource use, Patient/societal consequences of poor quality

**1c.2. If Other:**

**1c.3. Provide epidemiologic or resource use data that demonstrates the measure addresses a high priority aspect of healthcare.**

**List citations in 1c.4.**

Safety concerns arising from clinical trials of ESA treatment of anemia of chronic kidney disease (CKD) have led to recent changes in FDA recommendations on ESA use in patients with CKD. In addition, changes in financial incentives for treatment of anemia following the implementation of the revised Medicare ESRD Prospective Payment System have further heightened concerns in the dialysis community that patients with CKD-related anemia may be denied adequate access to ESAs for prevention of red blood cell transfusion. This concern has been further amplified by recently reported trends in anemia management in US chronic dialysis patients, demonstrating rapid declines in achieved hemoglobin from mid-2010 to the present.

The risks associated with aggressive treatment of anemia of CKD with ESAs have been well documented in KDIGO Anemia Management Guidelines as well as in updated FDA package insert information for ESAs. In contrast, the effect of anemia management paradigms that target to lower hemoglobin levels, and generally use less ESA, on transfusion risk is less well defined. Several clinical interventional trials comparing higher vs. lower hemoglobin targets have shown higher transfusion rates in those patients randomized to lower hemoglobin targets. The importance of these observations is limited by lack of predefined criteria for use of blood transfusion in most studies.

It has 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 inverse relationship between achieved hemoglobin and transfusion events has been reported previously for Medicare dialysis patients ( Ma 1999) and for non-dialysis CKD patients treated in the Veterans Administration system (Lawler 2010)

Unpublished analyses of Medicare Claims data presented at CMS Technical Expert Panel in May 2012 demonstrate an inverse association between achieved hemoglobin and subsequent transfusion risk using more recent data from 2008-2011.

In early 2012, a highly publicized USRDS study presented at the NKF Clinical meeting reported increased dialysis patient transfusion rates in 2011 compared to 2010.

UM-KECC and Arbor Research collaborators presented an analysis of transfusion events in Medicare dialysis patients from 2009-2011, observing increased transfusions in 2011, although the magnitude of change in transfusion rates was much lower than reported by the USRDS.

**1c.4. Citations for data demonstrating high priority provided in 1a.3**

Lawler EV, Bradbury BD, Fonda JR, et al. "Transfusion burden among patients with chronic kidney disease and anemia." *Clinical journal of the American Society of Nephrology : CJASN* (2010) 5:667-72. PMID: 20299366

Ma JZ, Ebben J, Xia H, et al. "Hematocrit level and associated mortality in hemodialysis patients." *Journal of the American Society of Nephrology : JASN* (1999) 10:610-9. PMID: 10073612

**1c.5. If a PRO-PM (e.g. HRQoL/functional status, symptom/burden, experience with care, health-related behaviors), provide evidence that the target population values the measured PRO and finds it meaningful. (Describe how and from whom their input was obtained.)**

N/A

## 2. Reliability and 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. ***Measures must be judged to meet the subcriteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.***

**2a.1. Specifications** The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

**De.5. Subject/Topic Area** (check all the areas that apply):

Renal, Renal : End Stage Renal Disease (ESRD)

**De.6. Cross Cutting Areas** (check all the areas that apply):

**S.1. Measure-specific Web Page** (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

**S.2a. If this is an eMeasure**, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure Attachment:

**S.2b. Data Dictionary, Code Table, or Value Sets** (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment Attachment: STrR\_Code\_Table-635605475147100397.xlsx

**S.3. For endorsement maintenance**, please briefly describe any changes to the measure specifications since last endorsement date and explain the reasons.

N/A

**S.4. Numerator Statement** (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome)

**IF an OUTCOME MEASURE**, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Number of eligible observed red blood cell transfusion events. Events are defined as transfer of one or more units of blood or blood products into recipient's blood stream (code set is provided in the numerator details) among patients dialyzing at the facility during the inclusion episodes of the reporting period. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

**S.5. Time Period for Data** *(What is the time period in which data will be aggregated for the measure, e.g., 12 mo, 3 years, look back to August for flu vaccination? Note if there are different time periods for the numerator and denominator.)*

One year

**S.6. 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, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm.

Red blood cell transfusions are identified by in-patient records with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code = 37 or procedure code in (9903, 9904) and with out-patient records with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) and HCPCS code in (P9010, P9011, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9058, 36430).

The numerator is calculated using Medicare Claims data. Transfusion events are identified by using the above mentioned codes and then the patient is attributed to a dialysis facility using the rules discussed in the denominator details (S.9). The numerator is the count of all such eligible transfusion events over the inclusion periods as defined below in section S.11, for a given facility.

Our method for counting transfusion events relies on a conservative counting algorithm and, because of the way transfusion information is reported in Medicare claims, we use different rules for counting transfusion events, depending on whether or not the event occurs in the inpatient setting, or an outpatient setting. The most common way events are reported on claims is by reporting a revenue center or value code (inpatient claims) or for outpatient claims, reporting HCPCS codes for a revenue center date.

One "transfusion event" is counted per inpatient claim if one or more transfusion-related revenue center or value codes are present. This is the way most inpatient transfusion events are reported on claims (i.e., using revenue center or value codes, not procedure codes). We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center and value codes reported so that the number of discrete events counted is the same whether the claim indicates 1 unit of blood or multiple units of blood. This results in a very conservative estimate of blood transfusions from inpatient claims. A small fraction of inpatient transfusion events are identified using specific procedure codes. For these cases, we are able to identify multiple transfusion events for some hospitalizations and count a unique "transfusion event" for each transfusion procedure code listed on an inpatient claim. CMS allows the transfusion procedure to be billed only once per day per visit.

Transfusion events are not common in outpatient settings, but similar rules apply. Multiple HCPCS codes reported for the same revenue center date are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, 3 pints of blood reported with the same revenue center date would be counted as a single transfusion event.

The detailed procedures to determine unique transfusion events at the claim level are presented in a flow chart in the Appendix.

**S.7. Denominator Statement** *(Brief, narrative description of the target population being measured)*

Number of eligible red blood cell transfusion events (as defined in the numerator statement) that would be expected among patients at a facility during the reporting period, given the patient mix at the facility. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

**S.8. Target Population Category** *(Check all the populations for which the measure is specified and tested if any):*

Populations at Risk

**S.9. Denominator Details** *(All information required to identify and calculate the target population/denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

Starting with day 91 after onset of ESRD, a patient is attributed to a facility once the patient has been treated there for the past 60 days and for the following 60 days after transfer to another dialysis facility.

Based on a risk adjustment model for the overall national transfusion rates, we compute the expected number of red blood cell



transfusion events for each patient attributed to a given facility. The sum of all such expectations over patients in a facility yields the overall expected number of transfusions for a given facility given the specific patient mix. This forms the denominator of the measure. This measure is based on Medicare administrative claims and databases and is applied to patients covered by Medicare.

**S.10. Denominator Exclusions** *(Brief narrative description of exclusions from the target population)*

All transfusions associated with transplant hospitalization are excluded. Patients are excluded if they have a Medicare claim for hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, and sickle cell anemia within one year of their patient at risk time. Since these comorbidities are associated with higher risk of transfusion and require different anemia management practices that the measure is not intended to address, every patient's risk window is modified to have at least 1 year free of claims that contain diagnoses on the exclusion list.

**S.11. Denominator Exclusion Details** *(All information required to identify and calculate exclusions from the denominator such as definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)*

All transfusions associated with transplant hospitalization are excluded. Patients are excluded if they have a Medicare claim for hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, and sickle cell anemia within one year of their patient at risk time. Since these comorbidities are associated with higher risk of transfusion and require different anemia management practices that the measure is not intended to address, every patient's risk window is modified to have at least 1 year free of claims that contain diagnoses on the exclusion list.

We performed multivariate logistic regression demonstrating that a 1-year look back period for the above mentioned comorbidities was more predictive of transfusion events compared to longer look back periods.. The figure found in the appendix describes the inclusion and exclusion period of a hypothetical patient. In the figure included in the appendix, a hypothetical patient has patient years at risk at a facility from 1/1/2008 to 12/31/2011. Review of Medicare claims identified presence of one or more exclusion comorbidities (see above and Appendix) in 2007 (Claim1), 2008 (Claim2) and 2010 (Claim3). Each claim is followed by a one year exclusion period. The revised inclusion periods are defined as risk windows with at least a 1 year claim-free period (Inclusion1 and Inclusion2 in Figure1). The patient has two transfusion events, marked as T1 and T2 in late 2008 and late 2011 respectively. However, since T1 falls in the exclusion period, it will not be counted towards the facility's transfusion count as presence of exclusion comorbidity claims within a year might have increased the risk of transfusion unrelated to dialysis facility anemia management practice. However, T2, which occurs in late 2011 and in Inclusion2 period, will be counted since there is at least a year gap between this transfusion event and the last claim observed.

**S.12. Stratification Details/Variables** *(All information required to stratify the measure results including the stratification variables, definitions, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b)*

N/A

**S.13. Risk Adjustment Type** (Select type. Provide specifications for risk stratification in S.12 and for statistical model in S.14-15)

Statistical risk model

If other:

**S.14. Identify the statistical risk model method and variables** *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development and testing should be addressed with measure testing under Scientific Acceptability)*

The denominator of the "STrR" uses expected transfusions calculated from a Cox model (Cox, 1972) as extended to handle repeated events (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). For computational purposes, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and computational methodology as developed in Liu, Schaubel and Kalbfleisch (2010). A stage 1 model is first fitted to the national data with piecewise-constant baseline rates stratified by facility; transfusion rates are adjusted for patient age, diabetes, duration of ESRD, nursing home status, BMI at incidence, comorbidity index at incidence, and calendar year. This model allows the baseline transfusion rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The linear predictor for each patient based on the regression coefficients in the stage 1 model is used to

compute a risk adjustment factor that is then used as an offset in the stage 2 model.

References:

- Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society, Series B, 34, 187-220.
- Cook, R. and Lawless, J. The Statistical Analysis of Recurrent Events. New York: Springer. 2007.
- Cook, R. and Lawless, J. Marginal analysis of recurrent events and a terminal event. Statistics in Medicine 1997; 16: 911-924.
- Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.
- Lawless, J. F. and Nadeau, C. Some simple and robust methods for the analysis of recurrent events, Technometrics, 37 1995, 355-364.
- Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. Semi parametric regression for the mean and rate functions of recurrent events, Journal of the Royal Statistical Society Series B, 62, 2000, 771-730
- Liu, D., Schaubel, D.E. and Kalbfleisch, J.D. Computationally efficient marginal models for clustered recurrent event data, University of Michigan Department of Biostatistics Technical Reports, 2010.

**S.15. Detailed risk model specifications** (must be in attached data dictionary/code list Excel or csv file. Also indicate if available at measure-specific URL identified in S.1.)

*Note: Risk model details (including coefficients, equations, codes with descriptors, definitions), should be provided on a separate worksheet in the suggested format in the Excel or csv file with data dictionary/code lists at S.2b.*

Provided in response box S.15a

**S.15a. Detailed risk model specifications** (if not provided in excel or csv file at S.2b)

The patient characteristics included in the stage 1 model as covariates are:

Age (18-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old)

Cause of ESRD (diabetes or other)

Nursing home status (Nursing home status is identified as in or not in a nursing home in the previous calendar year)

BMI at incidence

Comorbidity index at incidence

Duration of ESRD (91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date)

Calendar year.

The comorbidity index is calculated as a weighted linear combination of comorbidities reported on the Medical Evidence Form (CMS-2728) namely:

alcohol dependence

atherosclerotic heart disease

cerebrovascular disease

chronic obstructive pulmonary disease

congestive heart failure

diabetes

diabetes (currently on insulin)

drug dependence

inability to ambulate

inability to transfer

malignant neoplasm

Cancer

other cardiac disease

peripheral vascular disease

tobacco use (current smoker)

Using the same weights as used for Standardized Hospitalization Ratio (see [www.dialysisdata.org](http://www.dialysisdata.org); NQF #1463

<http://www.qualityforum.org/QPS/1463>). BMI is included as a log-linear term. Categorical indicator variables are included as covariates in the stage 1 model to flag records with missing values for cause of ESRD, comorbidity index, and BMI. These variables



have a value of 1 if the patient is missing the corresponding piece of information and a value of 0 otherwise. Another categorical indicator variable included as a covariate to flag records where the comorbidity index is 0 has a value of 1 if the patient has a comorbidity index of 0 and a value of 0 otherwise. Beside main effects, some two way interaction terms are also included in the model based on their clinical and statistical significance.

**S.16. Type of score:**

Ratio

If other:

**S.17. 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 = Lower score

**S.18. 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.*)

Numerator is the observed number of transfusion events for a facility and denominator for the same facility is the expected number of transfusion events adjusted for patient mix. The measure for a given facility is calculated by dividing the numerator by the denominator.

**S.19. Calculation Algorithm/Measure Logic Diagram URL or Attachment** (*You also may provide a diagram of the Calculation Algorithm/Measure Logic described above at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1*)

Available in attached appendix at A.1

**S.20. Sampling** (*If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.*)

IF a PRO-PM, identify whether (and how) proxy responses are allowed.

N/A

**S.21. Survey/Patient-reported data** (*If measure is based on a survey, provide instructions for conducting the survey and guidance on minimum response rate.*)

IF a PRO-PM, specify calculation of response rates to be reported with performance measure results.

N/A

**S.22. Missing data** (specify how missing data are handled, e.g., imputation, delete case.)

Required for Composites and PRO-PMs.

N/A

**S.23. Data Source** (*Check ONLY the sources for which the measure is SPECIFIED AND TESTED*).

If other, please describe in S.24.

Administrative claims, Electronic Clinical Data

**S.24. Data Source or Collection Instrument** (*Identify the specific data source/data collection instrument e.g. name of database, clinical registry, collection instrument, etc.*)

IF a PRO-PM, identify the specific PROM(s); and standard methods, modes, and languages of administration.

These data are part of an extensive and comprehensive national ESRD patient database, derived from the Consolidated Renal Operations in a Web-enabled Network (CROWN) data system, Medicare claims, and the Social Security Death Master File. The CROWN data system is made up of the Renal Management Information System (REMIS) and CROWNWeb and is updated regularly using the Medicare Enrollment Database (EDB), ESRD Medical Evidence Report forms (CMS 2728), ESRD Death Notification forms (CMS 2746), and the Organ Procurement and Transplantation Network (OPTN) transplant database.

**S.25. Data Source or Collection Instrument** (*available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1*)

No data collection instrument provided

**S.26. Level of Analysis** (Check *ONLY* the levels of analysis for which the measure is SPECIFIED AND TESTED)

Facility

**S.27. Care Setting** (Check *ONLY* the settings for which the measure is SPECIFIED AND TESTED)

Dialysis Facility

If other:

**S.28. COMPOSITE Performance Measure** - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.)

N/A

**2a. Reliability** – See attached Measure Testing Submission Form

**2b. Validity** – See attached Measure Testing Submission Form

STrR\_NQF\_Testing.docx

### 3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

#### 3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

##### 3a.1. Data Elements Generated as Byproduct of Care Processes.

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score)

If other:

#### 3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

**3b.1. To what extent are the specified data elements available electronically in defined fields?** (i.e., data elements that are needed to compute the performance measure score are in defined, computer-readable fields)

ALL data elements are in defined fields in a combination of electronic sources

**3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources.**

**3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL.**

Attachment:

#### 3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

**3c.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.**

**IF a PRO-PM, consider implications for both individuals providing PROM data (patients, service recipients, respondents) and those**

whose performance is being measured.

N/A

**3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (e.g., value/code set, risk model, programming code, algorithm).**

N/A

## 4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of high-quality, efficient healthcare for individuals or populations.

### 4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

#### 4.1. Current and Planned Use

*NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.*

Planned	Current Use (for current use provide URL)
Payment Program	Public Reporting Dialysis Facility Compare <a href="http://qa.medicare.gov/dialysisfacilitycompare/#">http://qa.medicare.gov/dialysisfacilitycompare/#</a>

#### 4a.1. For each CURRENT use, checked above, provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included

DFC:

Purpose: Dialysis Facility Compare helps patients find detailed information about Medicare-certified dialysis facilities. They can compare the services and the quality of care that facilities provide.

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities who are eligible for the measure, and have at least 11 patients (due to public reporting requirements). For the most recent DFC report, that was 5355 facilities.

Patients included: All patients who meet the requirements to be included in the measure from included facilities.

QIP:

Purpose: The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The measure has been finalized for PY2018.

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities who are eligible for the measure, and have at least 11 patients (due to public reporting requirements). Number of accountable entities: All Medicare-certified dialysis facilities who are eligible for the measure, and have at least 11 patients (due to public reporting requirements). For the most recent QIP report, 5410 received reports.

Patients included: All patients who meet the requirements to be included in the measure from included facilities.

**4a.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons?** (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?)

N/A

**4a.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement.** (Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.)

N/A

#### 4b. Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

##### 4b.1. Progress on Improvement. (Not required for initial endorsement unless available.)

Performance results on this measure (current and over time) should be provided in 1b.2 and 1b.4. Discuss:

- Progress (trends in performance results, number and percentage of people receiving high-quality healthcare)
- Geographic area and number and percentage of accountable entities and patients included

N/A

**4b.2. If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.**

CMS is currently reporting this measure on Dialysis Facility Compare (as of January 2014). This measure has also been finalized for for PY2018 QIP. Given that the measure has only been publically reported for a short time, progress on improvement could not be evaluated. We anticipate that public reporting of this measure would improve patient outcomes, given that blood transfusion has been linked to survival indirectly via patient access to transplantation. Studies have shown superior patient survival with kidney transplantation compared to chronic dialysis. See 1a.3 for more information.

#### 4c. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

**4c.1. Were any unintended negative consequences to individuals or populations identified during testing; OR has evidence of unintended negative consequences to individuals or populations been reported since implementation? If so, identify the negative unintended consequences and describe how benefits outweigh them or actions taken to mitigate them.**

N/A

## 5. Comparison to Related or Competing Measures

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.

### 5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

No

#### 5.1a. List of related or competing measures (selected from NQF-endorsed measures)

**5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.**

**5a. Harmonization**

The measure specifications are harmonized with related measures;

**OR**

The differences in specifications are justified

**5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):**

**Are the measure specifications completely harmonized?**

**5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.**

**5b. Competing Measures**

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure);

**OR**

Multiple measures are justified.

**5b.1. If this measure conceptually addresses 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.)**

**Appendix**

**A.1 Supplemental materials may be provided in an appendix.** All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

[Attachment Attachment: STrR\\_appendix-635605502365187509.pdf](#)

**Contact Information**

**Co.1 Measure Steward (Intellectual Property Owner):** Centers for Medicare & Medicaid Services

**Co.2 Point of Contact:** Helen, Dollar-Maples, [Helen.Dollar-Maples@cms.hhs.gov](mailto:Helen.Dollar-Maples@cms.hhs.gov), 410-786-7214-

**Co.3 Measure Developer if different from Measure Steward:** University of Michigan Kidney Epidemiology and Cost Center

**Co.4 Point of Contact:** Casey, Parrotte, [parrotte@med.umich.edu](mailto:parrotte@med.umich.edu)

**Additional Information**

**Ad.1 Workgroup/Expert Panel involved in measure development**

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

**Measure Developer/Steward Updates and Ongoing Maintenance**

**Ad.2 Year the measure was first released:** 2015

**Ad.3 Month and Year of most recent revision:** 02, 2015

**Ad.4 What is your frequency for review/update of this measure?** Annually

**Ad.5 When is the next scheduled review/update for this measure?** 02, 2016

**Ad.6 Copyright statement:**

**Ad.7 Disclaimers:**

**Ad.8 Additional Information/Comments:**