March 26, 2020

National Quality Forum
1099 14th Street NW
Suite 500
Washington DC 20005

RE: NQF Renal Project, Fall 2019 Cycle

Kidney Care Partners (KCP) appreciates the opportunity to comment on the single measure under consideration for endorsement in the National Quality Forum's (NQF) Renal Project Fall 2019 Cycle, *NQF 2979: Standardized Transfusion Ratio for Dialysis Facilities* (STrR) from the Centers for Medicare and Medicaid (CMS). KCP is a coalition of more than 30 organizations comprised of patient advocates, dialysis professionals, care providers, researchers, and manufacturers, dedicated to working together to improve quality of care for individuals with Chronic Kidney Disease (CKD) and End-Stage Renal Disease (ESRD). We commend NQF for responding to KCP's August 2018 request for an ad hoc review, due to concerns about the measure's validity arising from the ICD-9 to ICD-10 conversion, by advancing an early full maintenance review of the STrR.

KCP supports and recognizes the importance and value of NQF's endorsement process to examine the importance, reliability, and validity of measures, and KCP appreciates the NQF Renal Standing Committee for its thoughtful deliberations on this measure. **Of note, KCP has reviewed the specifications and measure submission for the three versions of the STrR considered by NQF, which we provide in a side-by-side as attachment A; with only a few exceptions that we discuss in a following section, the specifications of the original 2014/15 version are identical to the current measure. We also have compared the codes used to denote a transfusion event in the 2014/15 version and the current 2019/20 version, and they are identical (attachment B).**

KCP has long recognized that proper anemia management is a critical component of high-quality dialysis care. We have consistently expressed concerns, however, about the implementation of the STrR in the ESRD Quality Improvement Program (QIP) due to technical issues we note in a later section. Perhaps most significantly, and the stated rationale underlying the Renal Standing Committee's rejection of the original measure in 2015, the measure is a more accurate reflection of transfusion practices and behaviors at the hospital level than the quality of care at dialysis facilities. KCP did then and continues now to concur with this assessment. We again note that because transfusions do not occur in dialysis facilities, it is difficult for facilities to influence whether a patient receives a transfusion. More importantly, despite repeated requests to CMS, dialysis facilities still do not have access to the hospital transfusion data that would both allow them to know when a transfusion occurred and enable them to enact robust quality improvement efforts to significantly improve clinical care and outcomes. Put simply, we believe there are better, more meaningful measures (e.g., a low hemoglobin measure) that

would provide a more accurate picture of anemia management of patients on dialysis, and we continue to encourage CMS to collaborate with KCP to engage the renal community in a more meaningful process for measure development and selection in this important area. We urge the Committee to reconsider its recommendation for endorsement.

STrR History

KCP believes it is important to document the "history" of the STrR because it has significant relevance to our comments and the Committee's (re)consideration of what is essentially the original, 2014/15 version of the STrR. As we have stated earlier, that version essentially matches the measure now under consideration.

In 2015, the Renal Standing Committee reviewed the STrR (then NQF 2699) and did not recommend the measure, due primarily to concerns about the potential for differential treatment of data from procedure and revenue codes and that the measure reflects transfusion practices and behaviors at the hospital level instead of quality of care at dialysis facilities.

The subsequent iteration of the measure, renumbered NQF 2979, had revised specifications to "more conservatively" (as stated by the developer) define transfusion events by removing the revenue codes and relying on ICD-9 codes. While the Committee's concerns about hospital- and physician-related factors remained unaddressed, the measure was nevertheless endorsed in December 2016. Due to the validity concerns raised by KCP with the subsequent ICD-9 to ICD-10 conversion, CMS has returned to the 2014/15 construction in its specifications. Accordingly, we submit that the Renal Committee's original concerns about the potential for differential treatment of data from procedure and revenue codes by different hospitals again (and still) applies, thereby threatening validity.

The balance of this letter sets forth KCP's additional concerns about the reliability of the measure (currently used in the QIP), in particular for small facilities, as well as technical concerns.

STrR is not Reliable in Small Facilities

In its submission to NQF for the 2014 version, which is now the 2019/20 specifications, CMS's reliability testing only included facilities with at least 10 patient-years at risk. IURs (a measure of reliability) for the 1-year STrR ranged from 0.49-0.55, indicating that 1/2 of variation in the 1-year STrR could be attributed to between-facility differences (signal) and 1/2 to within-facility variation (noise). This is traditionally interpreted as a low-to-moderate degree of reliability;[1] however, when stratified by facility size, CMS's own data yield IURs for small facilities ranged from 0.36-0.44—an "unacceptable" level of reliability.

[1] Note: While standards for what is a "good" level of reliability can vary and depend on your theoretical knowledge of the scale in question, many methodologists interpret IURs and ICCs of <0.5 as "unacceptable" (with between 0.50-0.75 moderate, 0.75-0.90 good, >0.90 excellent). See, for instance, Koo TK, Li MY, "A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research". *Journal of Chiropractic Medicine*. 2016;15(2):155–163.

	2009		2010		2011		2012	
Facility Size (Number of patients)	IUR	N	IUR	N	IUR	N	IUR	N
All	**0.49**	4797	**0.53**	4985	**0.55**	5117	**0.54**	5278
Small (<=46)	**0.36**	1513	**0.44**	1576	**0.38**	1706	**0.36**	1743
Medium (47–78)	**0.46**	1637	**0.49**	1682	**0.52**	1687	**0.54**	1817
Large (>=79)	**0.59**	1647	**0.6**	1727	**0.66**	1724	**0.65**	1718

In its submission to NQF for the 2019 version, CMS updated testing, but reported only a single overall IUR of 0.63 to 0.68 across all facilities, which traditionally corresponds to a moderate degree of reliability. While this is an improvement of the overall reliability statistic when compared to the 2014/15 submission, it is impossible to discern whether improvement in this aggregate statistic is a function of true reliability improvement or a greater number of large facilities.

In response to a question from the NQF Committee, the developer remarked that when stratifying by facility size, it found that, "as expected, larger facilities have greater IUR" (higher reliability). When further pressed, the developer stated that NQF "does not require" reporting of reliability by facility size.

We believe it's disingenuous, at best, not to provide reliability based on facility size, especially because CMS's own data *from the same version of the measure* demonstrated in 2014/15 that for small facilities (<=46), the IUR was 0.36. That is, for approximately 1/3 of facilities, the score that they receive on the 2014/15 STrR (which differs little from the 2019 STrR) could be attributed to 64% noise and 36% quality signal. KCP submits that the STrR, as currently specified, has unacceptable reliability for small facilities. We also strongly recommend that the NQF Renal Standing Committee specifically request updated reliability data stratified by facility size so it can determine whether small facilities should be excluded. Finally, we recommend that the Renal Standing Committee vote "Insufficient" on the Reliability criterion at this time due to these missing data.

Technical Issues with the STrR

Since the 2019/20 measure specifications have returned to the 2014/15 specifications, KCP offers the following technical comments:

- There is no adjustment for hospital- or physician-related factors; the measure could be improved by incorporating both into the risk model.
- The predictive model posits to reveal actual vs predicted rate, when the basis for the ratio comes from claims and not EMR data; documentation fails to demonstrate it accurately predicts and identifies those who have had a transfusion, only the ordering of blood or blood products.
- Transfusions do not occur in dialysis facilities; it is difficult for facilities to influence whether a patient receives a transfusion and they often do not know when a patient has received a transfusion. CMS should provide transfusion data directly to facilities on a quarterly basis using DFC calculations and the 6-month lagged data file.
- Transfusions are coded by hospitals and coding varies nationwide and even within hospitals. Coding is inconsistent between type and screens (*i.e.*, preparing for

transfusion) and actual transfusions. Some coding variations potentially overestimate number of transfusions, which would inappropriately penalize facilities in those areas. CMS should conduct an audit of transfusion data and adjust the measure accordingly.

Additionally, as previously noted, the 2019/20 specifications mirror the 2014/15 specifications for the most part. We noted three differences, however, and offer the following comments:

- Medicare Advantage patients are now excluded from the measure, which relies on claims data. KCP believes this poses a threat to the STrR's validity (and other measures that rely on claims data) and, moreover, MA patients are anticipated to be an increasing percentage of the population so the threat to validity is likely to become significant. Any one facility may be advantaged or disadvantaged by having a significant percentage of MA patients.

- A number of exclusions are no longer listed as such in the "exclusions" column of the specifications, but are included in the case identification algorithm submitted to NQF. We recommend the NQF Committee request explicit articulation in the specifications as exclusions per se, as has been done for other iterations of the measure and is commonly done for measures in many care areas; doing so is a much more transparent presentation.
- The exclusion for patients not treated by any facility for >= 1 year is not present in the 2019/20 specifications, but was in the earlier versions. It is unclear if this is an oversight or if it was intentionally removed. KCP recommends the NQF Committee seek clarification on this change and, if intentional, the justification.

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.530.9524).

Sincerely,

Kidney Care Partners

Akebia
American Kidney Fund, Inc.
American Nephrology Nurses Association
American Renal Associates
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen, Inc.
Ardelyx
AstraZeneca
Atlantic Dialysis Management Services, LLC
Baxter International, Inc.
Board of Nephrology Examiners Nursing Technology

B. Braun Medical, Inc.
Cara Therapeutics, Inc.
Centers for Dialysis Care
Corvidia Therapeutics, Inc.
DaVita, Inc.
Dialysis Patient Citizens, Inc.
DialyzeDirect
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Greenfield Health Systems
Kidney Care Council
Medtronic plc
National Kidney Foundation, Inc.
National Renal Administrators Association
Nephrology Nursing Certification Commission
Otsuka America Pharmaceutical, Inc.
Renal Physicians Association
Renal Support Network
Rockwell Medical
Rogosin Institute
Satellite Healthcare, Inc.
US Renal Care

STrR SPECIFICATIONS COMPARISON TABLE

Note: Revisions are tracked sequentially; redlines illustrate variations from the immediately preceding version. KCP notes in blue text.

	2014 SPECIFICATIONS (NQF 2966)	2016 ENDORSED SPECIFICATIONS (NQF 2979)	2019 REVISED SPECIFICATIONS (NQF 2979)
DESCRIPTION	Ratio of the number of eligible RBC transfusion events observed in patients dialyzing at a facility to the number of eligible transfusion events 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. The STrR is specified for all adult dialysis patients.	Ratio of the number of eligible RBC transfusion events observed in patients dialyzing at a facility to the number of eligible transfusion events 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. The STrR is specified for all adult dialysis patients. This measure is calculated as a ratio but can also be expressed as a rate.	Ratio of the number of eligible RBC transfusion events observed in patients dialyzing at a facility to the number of eligible transfusion events 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. The STrR is specified for all adult dialysis patients. This measure is calculated as a ratio but can also be expressed as a rate.
NUMERATOR	Number of eligible observed RBC transfusion events* among patients dialyzing at the facility during the inclusion episodes** of the reporting period. *Event: Transfer of >=1 unit(s) of blood or blood products into recipient's blood stream. **Inclusion episodes are those that do not have any claims pertaining to comorbidities identified for exclusion in the 1-year look back period prior to each observation window.	Number of eligible observed RBC transfusion events* among patients dialyzing at the facility during inclusion episodes** of the reporting period. *Event: Transfer of >=1 unit(s) of blood or blood products into recipient's blood stream. **Inclusion episodes: Episodes that do not have any claims pertaining to comorbidities identified for exclusion in the 1-year look-back period prior to each observation window.	Number of eligible observed RBC transfusion events* among patients dialyzing at the facility during inclusion episodes** of the reporting period. *Event: Transfer of >=1 unit(s) of blood or blood products into recipient's blood stream. **Inclusion episodes: Episodes that do not have any claims pertaining to comorbidities identified for exclusion in the 1-year look-back period prior to each observation window.
DENOMINATOR	Number of eligible RBC transfusion events that would be expected among patients at a facility during the reporting period, given the patient mix at the facility.	Number of eligible RBC transfusion events that would be expected among patients at a facility during the reporting period, given the patient mix at the facility.	Number of eligible RBC transfusion events that would be expected among patients at the facility during the reporting period, given the patient mix at the facility.
EXCLUSIONS	• Patients <18 years old. • Patients on ESRD treatment for <90 days. • Patients treated at the facility for <60 days. • Patients are excluded beginning 60 days after they recover renal function or withdraw from dialysis. • Patients who receive a transplant (exclusion begins 3 days prior to the date of transplant). • All transfusions associated with the transplant hospitalization. • Patients who have not been treated by any facility for a year or longer. • Patients with a Medicare claim for one of the following conditions in the past year: Hemolytic and	• Patients <18 years old. • Patients on ESRD treatment for <90 days. • Patients treated at the facility for <60 days. • Patients are excluded beginning 60 days after they recover renal function or withdraw from dialysis. • Patients who receive a transplant (exclusion begins 3 days prior to the date of transplant). • All transfusions associated with the transplant hospitalization. • Patients who have not been treated by any facility for a year or longer. • Patients with a Medicare claim for one of the following conditions in the past year: Hemolytic and	• • All transfusions associated with the transplant hospitalization. • • Patients with 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 1 year of their patient time at risk. Since these

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	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, or sickle cell anemia.	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, or sickle cell anemia.	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 these exclusion eligible diagnoses. **KCP NOTES:** • Several 2014 and 2016 versions' exclusions (first 5 bullets above) are not listed as exclusions *per se* in the 2019 specifications but are included in the case identification algorithm submitted to NQF. • We were unable to identify the exclusion for patients not treated at any dialysis facility for a year or longer; it is unclear if this was an oversight by CMS or it was intentionally removed.
CODES[1]	**Inpatient:** • ICD procedure code(s) OR • Value code OR • Revenue center code(s) **Outpatient:** • Revenue center code(s) PLUS procedure code(s) OR • Value Code	**Inpatient:** • ICD procedure code(s) OR • Value code **Outpatient:** • Revenue center code(s) PLUS procedure code(s) OR • Value code **KCP NOTE:** Revenue codes were removed and ICD-10 codes corresponding to previously specified ICD-9 codes were added. Per CMS, revenue codes were removed to "tighten" transfusion definition.	**Inpatient:** • ICD procedure code(s) OR • Value code OR • Revenue center code(s) **Outpatient:** • Revenue center code(s) PLUS procedure code(s) OR • Value Code **KCP NOTE:** Revenue codes were reinserted, unchanged from 2014 version; ICD codes unchanged from prior versions.
RISK VARIABLES	• Patient age • Diabetes mellitus as primary cause of ESRD • Duration of ESRD • Nursing home status in previous calendar year • BMI at incidence of ESRD • Comorbidities at incidence of ESRD (ETOH dependence, atherosclerotic heart disease, cerebrovascular disease, COPD, CHF, diabetes [currently on insulin, on oral meds, w/o meds, and diabetic retinopathy], drug dependence, inability to	• Patient age • Diabetes mellitus as primary cause of ESRD • Duration of ESRD • Nursing home status in previous calendar year • BMI at incidence of ESRD • Comorbidities at incidence of ESRD (ETOH dependence, atherosclerotic heart disease, cerebrovascular disease, COPD, CHF, diabetes [currently on insulin, on oral meds, w/o meds, and diabetic retinopathy], drug dependence, inability to	• Patient age • Diabetes mellitus as primary cause of ESRD • Duration of ESRD • Nursing home status in previous calendar year • BMI at incidence of ESRD • Comorbidities at incidence of ESRD (ETOH dependence, atherosclerotic heart disease, cerebrovascular disease, COPD, CHF, diabetes [currently on insulin, on oral meds, w/o meds, and diabetic retinopathy], drug dependence, inability to

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[1] See Excel document submitted by the developer for codes and descriptions.

	2014 SPECIFICATIONS (NQF 2966)	2016 ENDORSED SPECIFICATIONS (NQF 2979)	2019 REVISED SPECIFICATIONS (NQF 2979)
	ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, PVD, current smoker) (each comorbidity included as a separate variable in risk model) • Calendar year • Categorical indicators for missing values for cause of ESRD, comorbidity index, and BMI and categorical indicator for comorbidity index is 0 • 2-way interaction terms: ○ Diabetes as cause of ESRD * Duration of ESRD ○ Age * Diabetes as cause of ESRD	ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, PVD, current smoker) (each comorbidity included as a separate variable in risk model) • Calendar year • Categorical indicators for missing values for cause of ESRD, comorbidity index, and BMI and categorical indicator for comorbidity index is 0 • 2-way interaction terms: ○ Diabetes as cause of ESRD * Duration of ESRD ○ Age * Diabetes as cause of ESRD	ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, PVD, current smoker) (each comorbidity included as a separate variable in risk model) • Calendar year • Categorical indicators for missing values for cause of ESRD, comorbidity index, and BMI and categorical indicator for comorbidity index is 0 • 2-way interaction terms: ○ Diabetes as cause of ESRD * Duration of ESRD ○ Age * Diabetes as cause of ESRD
ADDITIONAL INFORMATION	• Minimum data requirements = Facilities with at least 10 patient-years at risk will be eligible to receive a score on the measure. • Eligible transfusion events 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. • When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days, at which point the patient is attributed to the destination facility. • A patient-month is considered eligible if it is within two months of a month in which a patient has $900 of Medicare-paid dialysis claims or at least one Medicare-paid inpatient claim. • Data sources = Medicare claims, REMIS, CROWNWeb, Form 2728 to obtain the date of ESRD, and other CMS ESRD administrative data.	• Minimum data requirements = Facilities with at least 10 patient-years at risk will be eligible to receive a score on the measure. • Eligible transfusion events 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. • When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days, at which point the patient is attributed to the destination facility. • A patient-month is considered eligible if it is within two months of a month in which a patient has $900 of Medicare-paid dialysis claims or at least one Medicare-paid inpatient claim. • Data sources = Medicare claims, REMIS, CROWNWeb, Form 2728 to obtain the date of ESRD, and other CMS ESRD administrative data.	• Minimum data requirements = Facilities with at least 10 patient-years at risk will be eligible to receive a score on the measure. • Eligible transfusion events 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. • When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days, at which point the patient is attributed to the destination facility. • A patient-month is considered eligible if it is within two months of a month in which a patient has $900 of Medicare-paid dialysis claims or at least one Medicare-paid inpatient claim. Excludes all Medicare Advantage patients' time-at-risk from both the numerator and denominator. This change is to mitigate the potential bias associated with inclusion of MA patients derived from the absence of complete outpatient claims data for MA patients, severely limiting the identification of outpatient transfusion events for these individuals and eliminating a key source for claims-based exclusion comorbidities. • Data sources = Medicare claims, REMIS, CROWNWeb, Form 2728 to obtain the date of ESRD, and other CMS ESRD administrative data. **KCP NOTE:** The potential new and escalating (as enrollment grows) threat to measure validity resulting from the exclusion of Medicare Advantage patients has not been addressed by CMS.

<table>
<tr><th></th><th>2014 SPECIFICATIONS
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(NQF 2979)</th><th>2019 REVISED SPECIFICATIONS
(NQF 2979)</th></tr>
<tr>
<td>RELIABILITY</td>
<td>
Data January 1, 2009 – December 31, 2012.

Because the STrR is not a simple average, CMS reports that it estimates the IUR using a bootstrap approach using a resampling scheme to estimate within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

The STrR calculation only included facilities with at least 10 patient-years at risk. IURs for the 1-year STrR ranged from 0.49-0.55, indicating that 1/2 of variation in the 1-year STrR can be attributed to between-facility differences and 1/2 to within-facility variation. This is traditionally interpreted as a low-to-moderate degree of reliability.[2]
<table>
<tr><th></th><th>2009</th><th></th><th>2010</th><th></th><th>2011</th><th></th><th>2012</th><th></th></tr>
<tr><th>Facility Size (Number of patients)</th><th>IUR</th><th>N</th><th>IUR</th><th>N</th><th>IUR</th><th>N</th><th>IUR</th><th>N</th></tr>
<tr><td>All</td><td>0.49</td><td>4797</td><td>0.53</td><td>4985</td><td>0.55</td><td>5117</td><td>0.54</td><td>5278</td></tr>
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KCP NOTE: We note that while overall reliability (across all facilities) can be interpreted as “low-to-moderate”, <u>when stratified by facility size, IURs for small facilities ranged from 0.36-0.44—an “unacceptable” level of reliability.</u>
</td>
<td>
Data January 1, 2011 – December 31, 2014.

Because the STrR is not a simple average, CMS reports that it estimates the IUR using a bootstrap approach using a resampling scheme to estimate within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

The STrR calculation only included facilities with at least 10 patient-years at risk. IURs for the 1-year STrR ranged from 0.60-0.66, indicating that approximately 2/3 of variation in the 1-year STrR can be attributed to between-facility differences and 1/3 to within-facility variation. This is traditionally interpreted as a moderate degree of reliability.

Table 11: IUR for One-year STrR, Overall and by Facility Size, 2011-2014.
<table>
<tr><th></th><th>2011</th><th></th><th>2012</th><th></th><th>2013</th><th></th><th>2014</th><th></th></tr>
<tr><th>Facility Size</th><th>IUR</th><th>N</th><th>IUR</th><th>N</th><th>IUR</th><th>N</th><th>IUR</th><th>N</th></tr>
<tr><td>All</td><td>0.64</td><td>5142</td><td>0.66</td><td>5319</td><td>0.65</td><td>5442</td><td>0.60</td><td>5651</td></tr>
<tr><td>Small (<=46)</td><td>0.41</td><td>1714</td><td>0.41</td><td>1828</td><td>0.39</td><td>1840</td><td>0.30</td><td>1934</td></tr>
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</table>

KCP NOTE: We note that while overall reliability (across all facilities) can be interpreted as “moderate”, <u>when stratified by facility size, IURs for small facilities</u>
</td>
<td>
Data January 1, 2014 – December 31, 2017.

Because the STrR is not a simple average, CMS reports that it estimates the IUR using a bootstrap approach using a resampling scheme to estimate within facility variation that cannot be directly estimated by ANOVA. A small IUR (near 0) reveals that most of the variation of the measures between facilities is driven by random noise, indicating the measure would not be a good characterization of the differences among facilities, whereas a large IUR (near 1) indicates that most of the variation between facilities is due to the real difference between facilities.

The STrR calculation only included facilities with at least 10 patient-years at risk. IURs for the 1-year STrR ranged from 0.63-0.68, indicating that approximately 2/3 of variation in the 1-year STrR can be attributed to between-facility differences and 1/3 to within-facility variation. This is traditionally interpreted as a moderate degree of reliability.

KCP NOTE: While CMS indicates in the 2019 submission materials that, “as expected, larger facilities have a greater IUR”, <u>IURs were not explicitly demonstrated by facility size as in prior versions</u>, <u>making it impossible to stakeholders to determine if reliability remains “unacceptable” at small facilities (n <=46).</u> CMS presents no evidence to suggest this is no longer the case, noting only that this information is not required by NQF.
</td>
</tr>
</table>

[2] Note: While standards for what is a “good” level of reliability can vary and depend on your theoretical knowledge of the scale in question, many methodologists interpret IURs and ICCs of <0.5 as “unacceptable” (with between 0.50-0.75 moderate, 0.75-0.90 good, >0.90 excellent). See, for instance, Koo TK, Li MY. "A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research". *Journal of Chiropractic Medicine*. 2016;15(2):155–163.

	2014 SPECIFICATIONS (NQF 2966)	2016 ENDORSED SPECIFICATIONS (NQF 2979)	2019 REVISED SPECIFICATIONS (NQF 2979)
		ranged from 0.30-0.41—an "unacceptable" level of reliability.	
VALIDITY	**SMR, SRR, and SHR Association**: CMS asserts that STrR validity is supported by its association with other known quality measures, including both dialysis facility outcomes and practices. Spearman's rho is reported for all measures. For year 2012, the measure was found to be positively correlated with the 1-year SHR (rho = 0.40, p < .0001), the 1-year SMR (rho = 0.23, p < .0001), and the 1-year SRR (rho = 0.17, p < .0001). CMS interprets that these positive correlations indicate that facilities with more transfusions than would be expected based on national rates also have higher mortality, hospitalization, and readmission rates than would be expected. ++ **Hgb Association**: A negative correlation with average Hgb values of all ESA-treated dialysis patients was found (rho = -0.16, p < .0001), indicating that lower values of Hgb are associated with higher values of STrR, as expected. Similarly, a positive correlation with percent of patients with Hgb <10 (rho = 0.20, p < .0001) indicates that a higher percentage of patients with Hgb values <10 is associated with a higher STrR, as expected. ++ **Vascular Access Association**: The STrR was also found to be positively correlated with catheter use (rho =0.22, p < .0001) and negatively correlated with AVF use, suggesting that higher STrR values are associated with	**SMR and SHR Association**: Validity was assessed using Poisson regression models to measure the association between the 2014 SMR (NQF 0369) and SHR (NQF 1463) and the following tertiles of STrR: • T1: 0-<0.66 (reference) • T2: 0.66-<1.15 • T3: 1.15-<5.66 CMS reports results indicate the STrR was significantly associated with risk of mortality and hospitalization. For the 2014 SMR, RR of mortality increased as STrR tertiles increased from the reference group (tertile 1). For tertile 2, RR=1.06 (95% CI: 1.04, 1.08; p<0.001), and for tertile 3, RR=1.14 (95% CI: 1.12, 1.16; p<0.001). Similarly, for the 2014 SHR, RR of hospitalization increased with STrR tertiles, with the lowest risk in tertile 1. For tertile 2, RR=1.11 (95% CI: 1.10, 1.11; p<0.001), and for tertile 3, RR=1.29 (95% CI: 1.29, 1.30; p<0.001). CMS interprets that these positive correlations indicate that facilities with more transfusions than would be expected based on national rates also have higher standardized mortality and hospitalization rates than would be expected. ++ **Hgb <10 Association**: Validity was also assessed using a Poisson regression model to measure the association between facility level STrR and tertiles of % patients with Hgb <10: • T1: 3.7-<17.5% (reference) • T2: 17.5-<22.3% • T3: 22.3-<55.4% Percentage patients with Hgb <10 was found to be significantly associated with risk of transfusion, with RR of transfusion increasing with tertiles of % patients with Hgb <10. For Hgb tertile 2, RR=1.15 (95% CI: 1.13, 1.18; p<0.001), and for tertile 3, RR=1.31 (95% CI: 1.28, 1.33; p<0.001).	**SMR and SHR Association**: Validity was assessed using Poisson regression models to measure the association between the 2017 SMR (NQF 0369) and SHR (NQF 1463) and the following tertiles of STrR: • T1: 0-<0.70 (reference) • T2: 0.70-<1.13 • T3: 1.13-<7.1 CMS reports results indicate the STrR was significantly associated with risk of mortality and hospitalization. For the 2017 SMR, RR of mortality increased as STrR tertiles increased from the reference group (tertile 1). For tertile 2, RR=1.09 (95% CI: 1.07, 1.11; p<0.001), and for tertile 3, RR=1.17 (95% CI: 1.15, 1.19; p<0.001). Similarly, for the 2017 SHR, RR of hospitalization increased with STrR tertiles, with the lowest risk in tertile 1. For tertile 2, RR=1.15 (95% CI: 1.15, 1.16; p<0.001), and for tertile 3, RR=1.32 (95% CI: 1.32, 1.32; p<0.001). CMS interprets that these positive correlations indicate that facilities with more transfusions than would be expected based on national rates also have higher standardized mortality and hospitalization rates. ++ **Hgb <10 Association**: Validity was also assessed using a Poisson regression model to measure the association between facility level STrR and tertiles of % patients with Hgb <10: • T1: 3.7-<17.5% (reference) • T2: 17.5-<22.3% • T3: 22.3-<55.4% Percentage patients with Hgb <10 was found to be significantly associated with risk of transfusion, with RR of transfusion increasing with tertiles of % patients with Hgb <10. For Hgb tertile 2, RR=1.17 (95% CI: 1.15, 1.20; p<0.001), and for tertile 3, RR=1.44 (95% CI: 1.42, 1.47; p<0.001).

	2014 SPECIFICATIONS (NQF 2966)	2016 ENDORSED SPECIFICATIONS (NQF 2979)	2019 REVISED SPECIFICATIONS (NQF 2979)
	increased use of catheters and lower values with increased AVF use, as would be expected. ++ **Dialysis Adequacy Association:** The STrR was negatively correlated with percentage of patients with Kt/V >=1.2 (rho = -0.09, p < .0001), as would be expected. ++ **Face Validity:** 6 out of 6 voting members of CMS' 2012 Technical Expert Panel voted to recommend development of a facility-level Standardized Transfusion Ratio measure. The consensus recommendation of that clinical expert panel included the recommendation to include risk adjustment for conditions that are associated with an increased risk of blood transfusion such as hereditary anemia, chronic bone marrow failure conditions and active cancer.	CMS interprets these results demonstrate statistically significant stepwise differences in STrR across facility-level achieved Hgb tertiles, an intermediate outcome reflecting facility anemia management processes, suggesting "dose effect". ++ **Face Validity** (carried forward from previous NQF submission): 6 out of 6voting members of CMS's 2012 Technical Expert Panel voted to recommend development of a facility-level Standardized Transfusion Ratio measure. The consensus recommendation of that clinical expert panel included the recommendation to include risk adjustment for conditions that are associated with an increased risk of blood transfusion and in some cases, increased risk of ESA-associated adverse events, such as hereditary anemia, chronic bone marrow failure conditions and active cancer.	CMS interprets these results demonstrate statistically significant stepwise differences in STrR across facility-level achieved Hgb tertiles, an intermediate outcome reflecting facility anemia management processes, suggesting "dose effect". ++ **Face Validity** (carried forward from previous NQF submission): 6 out of 6voting members of CMS's 2012 Technical Expert Panel voted to recommend development of a facility-level Standardized Transfusion Ratio measure. The consensus recommendation of that clinical expert panel included the recommendation to include risk adjustment for conditions that are associated with an increased risk of blood transfusion and in some cases, increased risk of ESA-associated adverse events, such as hereditary anemia, chronic bone marrow failure conditions and active cancer.
NQF HISTORY	Never endorsed; reviewed and rejected by NQF in December 2015 secondary to concerns about potential differential treatment of data from procedure and revenue codes, and that the measure reflects transfusion practices and behaviors at the hospital level instead of quality of care at dialysis facilities.	Endorsed by NQF December 2016.	Submitted to NQF November 2019; supported by both MAP and Renal Standing Committee; currently out for member comment (tentatively March 11-April 9).