NATIONAL QUALITY FORUM
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Memo

November 17, 2020

To: Consensus Standards Approval Committee (CSAC)

From: Renal Project Team

Re: Renal Fall 2019 Track 2 Measures[a]

COVID-19 Updates

Considering the recent COVID-19 global pandemic, many organizations needed to focus their attention on the public health crisis. In order to provide greater flexibility for stakeholders and continue the important work in quality measurement, the National Quality Forum (NQF) extended commenting periods and adjusted measure endorsement timelines for the fall 2019 cycle.

Commenting periods for all measures evaluated in the fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks:

Track 1: Measures that Remained in Fall 2019 Cycle
Measures that did not receive public comments or only received comments in support of the Standing Committees' recommendations moved forward to the CSAC for review and discussion during its meeting on July 28-29, 2020.

- **Exceptions**
  Exceptions were granted to measures if non-supportive comments received during the extended post-comment period were similar to those received during the pre-evaluation meeting period and have already been adjudicated by the respective Standing Committees during the measure evaluation fall 2019 meetings.

Track 2: Measures Deferred to Spring 2020 Cycle
Fall 2019 measures that required further action or discussion from a Standing Committee were deferred to the spring 2020 cycle. This includes measures where consensus was not reached or those that require a response to public comments received. Measures undergoing maintenance review retained endorsement during that time. Track 2 measures will be reviewed by the CSAC in November.

During the CSAC meeting on November 17-18, 2020, the CSAC will review fall 2019 measures assigned to Track 2. Evaluation summaries for measures in Track 2 have been described in this memo and related Renal draft report. There were no Track 1 measures for the Renal Committee.

CSAC Action Required

The CSAC will review recommendations from the Renal project at its November 17-18, 2020 meeting

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and vote on whether to uphold the recommendations from the Committee.

This memo includes a summary of the project, measure recommendations, themes identified and responses to the public and member comments and the results from the NQF member expression of support. The following documents accompany this memo:

1. **Renal Fall 2019 Track 2 Draft Report**. The draft report includes measure evaluation details on all measures that followed Track 2. The complete draft report and supplemental materials are available on the project webpage. Measures that followed Track 1 have already been reviewed during the CSAC's meeting in July.
2. **Comment Table**. This table lists one comment received during the post-meeting comment period.

Background

Renal disease is a leading cause of morbidity and mortality in the United States. More than 20 million adults in the United States (10 percent of the population) have chronic kidney disease (CKD), which is associated with premature mortality, decreased quality of life, and increased healthcare costs. Risk factors for CKD include cardiovascular disease, diabetes, hypertension, and obesity. Untreated CKD can result in end-stage renal disease (ESRD). Currently, over half a million people in the United States have received a diagnosis of ESRD.

This project sought to identify and endorse performance measures for accountability and quality improvement that address conditions, treatments, interventions, or procedures relating to kidney disease.

On January 30, 2020, NQF convened a multistakeholder Standing Committee composed of 24 individuals to evaluate one measure undergoing maintenance review. The Committee recommended the measure for continued endorsement.

Draft Report

The Renal Fall 2019 Track 2 draft report presents the results of the evaluation of one measure considered under the Consensus Development Process (CDP). The measure is recommended for endorsement.

The measures were evaluated against the 2019 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	1	0	1
Measures recommended for endorsement	1	0	1

CSAC Action Required

Pursuant to the CDP, the CSAC is asked to consider endorsement of one candidate consensus measure.

Measures Recommended for Endorsement

- NQF 2979 Standardized Transfusion Ratio for Dialysis Facilities (University of Michigan Kidney Epidemiology and Cost Center)

Overall Suitability for Endorsement: Yes-14; No-1

Comments and Their Disposition

NQF received one comment from a member organization pertaining to the draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the NQF responses to each comment, is posted to the Renal project webpage.

Comments Received and NQF's Response

Measure-Specific Comments

2979: Standard Transfusion Ratio for Dialysis Facilities

KCP expressed several concerns related to attribution, noting that dialysis facilities do not have adequate control over the circumstances that dictate when and if a transfusion occurs. Commenter notes that while dialysis facilities have some ability to influence anemia, they suggest that other measures would be more appropriate to capture this. Commenter suggests that this would be more appropriate to attribute to hospitals. Commenter also called into question the reliability of the measure, especially for smaller dialysis facilities.

Measure Steward/Developer Response:

The current Standardized Transfusion Ratio was presented to NQF for both Ad Hoc review and Comprehensive Review in 2019/2020. The ad hoc review was motivated by a concern about validity rooted in acute care hospitals' shifting coding practices associated with conversion to ICD10 billing in October 2015. The earlier STrR prompting the ad hoc review, endorsed by NQF in 2016, relied on submission of transfusion ICD procedure codes (or a value code) only for identification of transfusion events. The coding shift artificially reduced the identification of transfusion events in hospitals that only submitted revenue center codes for inpatient transfusion events. To address the appropriate concern raised by the ad hoc review request, the measure that was passed by the Scientific Methods Panel and the Renal Standing Committee in 2019/2020 uses the original strategy for identification of transfusion events, first presented to NQF in 2015, effectively eliminating the validity concern raised in the ad hoc review request and in the concerns outlined in the public comment letter. Below we respond to these issues.

"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)."

Developer Response: We believe they must be referring to HCPCS codes used for outpatient transfusion events. For inpatient transfusion events, the current measure uses ICD10 procedure codes. The original measure used ICD9 procedure codes.

"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."

Developer Response: This potential issue was raised in the original 2015 review of STrR. Unfortunately, at the time, we had not completed additional analyses of the effect of hospital billing practices on identification of inpatient transfusion events. Before submitting the current 2019 measure with our original, broader definition of transfusion events, we addressed a concern raised by the Renal Standing Committee in 2015. The concern was about the possibility that hospital billing practice, i.e. use of procedure codes or failure to use procedure codes could have led to biased identification of inpatient transfusion events, undermining the scientific acceptability of the measure. Those analyses were performed as part of the developer's vetting of the STrR prior to re-submission for maintenance in 2019; the results were referred to in our introductory statement to the Renal Standing Committee in early 2020 when the measure was reviewed. We investigated all inpatient transfusion events over the four-year period 2014-2017, identifying every acute care hospital that provided an inpatient transfusion to one or more Medicare dialysis patient in any given year. We also identified the number of transfusion events at each hospital and the process(es) used by the hospital for claim submission of the transfusion event (i.e. with or without procedure code use). We then calculated the average number of transfusions per dialysis patient admission and summarized the results into three categories based on hospital "billing phenotype". In the unadjusted analysis, there was no difference in transfusion event per hospitalization for patients across the three billing phenotype categories. These results were confirmed using statistical modeling, predicting inpatient transfusion events with the three hospital "billing phenotype" categories as key covariates, and also adjusting for year, CMS region and hospital size (see table below).

Hospital-level Analysis for Inpatient Transfusions/Admissions in Relation to Hospital Transfusion Billing Practice during 2014-2017.

Covariates	Odd Ratio (95%CI)	P-value
% of transfusion events identified by revenue center codes only		
0-33%	ref	
34-67%	1.03 (1.01, 1.06)	0.015
68-100%	1.00 (0.98, 1.02)	0.935

The results of the logistic model reveal no meaningful association between hospital billing phenotype and transfusion frequency. On average, ESRD patients have nearly identical likelihood of receiving a blood transfusion during admission to hospitals with a wide range of transfusion billing phenotypes. Use of the original (2015) definition for transfusion events and reliance on revenue center codes along with procedure and value codes is not altered by hospital billing patterns associated with conversion to ICD10 and, unlike the restricted ("procedure code only") STrR version (endorsed in 2016), does not compromise transfusion event identification. Based on these results, it turns out that the theoretical concern raised by the Renal Standing Committee in 2015 regarding hospital effects was not substantiated. We do

not concur with the commenter's assessment. We do however, concur with the Renal Standing Committee's assessment that led to their recommendation to endorse the revised STrR in January 2020.

"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."

Developer Response: We addressed this in response to prior public comments. The argument raised is not accurate in that the individual patient lists and transfusion event counts at the facility level are available to facilities from UM-KECC's DFC help desk. In addition, identification of transfusion events from medical records summaries should be available to facilities if hospital and dialysis providers are appropriately communicating during patient transitions from inpatient to outpatient care settings after discharge. We note that these direct provider communications should be more timely and informative than claims-based information CMS could provide that would also be lagged by a period of time. In addition, the dialysis providers lead the anemia management efforts for this patient population. As we have indicated in the Evidence Form submitted with the revised measure and carefully reviewed and debated during the Renal Standing Committee, successful anemia management contributes significantly to transfusion avoidance. Since the dialysis facility is charged with anemia management for this population, most of the data required to enact "robust quality improvement efforts" are already in their possession.

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."

Developer Response: This is the same issue the commenter presented earlier in their letter. As addressed above we explain the similarities and differences between the current version (submitted in 2019) and the 2015 version. We also describe the in-depth 2019 analytic investigation performed to invalidate the hospital billing effect argument. The concern with hospital billing variation raised by the committee in 2015was not substantiated with empirical data.

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. 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."

Developer Response: All reliability testing was performed and submitted to NQF therefore no results are missing, as mistakenly asserted by the commenter. The NQF instructions require tests of signal to noise which were performed. NQF does not require submission of reliability testing stratified by facility size or other characteristics. The current STrR was passed for reliability by both the Scientific Methods Panel and the Renal Standing Committee, supporting the adequacy of our submission.

Given the established effect of sample size on IUR calculations, it is expected that large facilities will have higher IUR values and small facilities will have lower IUR values for any given measure. Using the empirical null method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size. That is, smaller

facilities have to have more extreme outcomes compared to other smaller facilities to be flagged. This additional methodologic protection is not reflected in the IUR results for small facilities.

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"

Developer Response: Addressed above. There is no evidence that a hospital level adjustment is needed, based on our own analyses. Second, the physician-level adjustment is not necessary because anemia management is included as a joint facility-nephrologist responsibility under the CfC 494 Medicare Conditions for Coverage, with reimbursement for anemia management at the facility level, not the practitioner level. The physician role in anemia management is as member of the dialysis facility's Interdisciplinary Care Team.

"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."

Developer Response: Many NQF-endorsed quality measures utilize Medicare Claims data to define a variety of events. Although EMR data sources are potentially a powerful source of event data, there has been only limited validation of their use to identify transfusion events to date. According to billing instructions, the revenue center codes used to bill for blood preparation and administration are only used for blood that is actually administered to the patient. Unless the commenter is proposing that there is a known practice of Medicare billing fraud in the submission of claims for administration of blood products, then their argument has very little impact on interpretation of the STrR results.

"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."

Developer Response: There is peer-review literature evidence that dialysis facilities can and do influence the transfusion-risk of their patients. Some of that literature is included in the Evidence Form submitted with the STrR re-evaluation. This point was discussed at length by the Renal Standing Committee in both 2016 and January 2020. We believe the results of their vote on evidence should stand. Regarding the request for provision of transfusion data directly to providers on a bi-annual timeline, that is a request that is not relevant to endorsement review of the STrR. Rather that is best negotiated directly between the dialysis facilities and their organizational affiliates and is not appropriate for brokerage through the NQF endorsement process.

"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."

Developer Response: Addressed above.

"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."

Developer Response: This point was explicitly reviewed and debated by the Renal Standing Committee during their January 2020 review. In preparing the 2019 submission for the Comprehensive Maintenance Review we addressed a bias issue related to the systematic absence of outpatient Medicare claims data for Medicare Advantage patients, a rapidly increasing subset of Medicare dialysis patients. The proposed STrR excludes Medicare Advantage patients for three reasons. First, we identified marked regional geographic variation in Medicare Advantage dialysis patients. Second, we confirmed that we are unable to identify outpatient transfusion events for these patients, noting that outpatient transfusions account for ~15% of all transfusions in the chronic dialysis population. Finally, the source for most claims-based diagnoses used for exclusion of patients from the STrR are derived from outpatient claims. Failure to exclude Medicare Advantage patients from this measure would significantly bias results for facilities with very high and very low fractions of MA patients. Exclusion of Medicare Advantage patients results in an unbiased assessment of facility performance regardless of the fraction of Medicare Advantage patients treated at the facility. The measure, as specified, is the most accurate and valid measure available to assess risk-adjusted transfusion events at the dialysis facility level.

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.

Developer Response: We believe that the specification details referred to by the commenter are fundamentally unchanged from prior versions of the STrR. We chose to document these details in the denominator detail rather than in the Exclusions to separate the concepts of exclusion from the measure due to specific comorbidity conditions from admit/discharge administrative exclusions in two separate areas for clarity and readability.

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

Developer Response: The measure calculation algorithm continues to exclude patient time at risk if not treated at any facility for > 1 year. If acceptable to NQF staff, we would be happy to clarify this point in the measure information form.

NQF Response:

The Renal Committee wishes to thank KCP for your thoughtful comment. The Renal Committee has carefully reviewed the substance of your comment as well as the developer's responses. Several items were discussed at length during the course of our measure evaluation meeting. We have clarified the remaining items with the developer to our satisfaction during the post-comment meeting and have recommended the measure for continued endorsement at this time.

Member Expression of Support

Throughout the continuous public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. No NQF members provided their expression of support or non-support.

Removal of NQF Endorsement

One measure, previously endorsed by NQF, has not been re-submitted, and endorsement has been removed.

Measure	Measure Description	Reason for Removal of Endorsement
0251 Vascular Access—Functional Arteriovenous Fistual (AVF) or AV Graft for Placement	Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who: 1) have a functional autogenour AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); 2) have a functional AV graft (computed and reported seperately); or 3) have a catheter, but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately). Reporting should be stratified by incident verses prevalent patients, as defined by USRDS.	Developer decided not to re-submit for endorsement.

Appendix A: CSAC Checklist

The table below lists the key considerations to inform the CSAC's review of the measures submitted for endorsement consideration.

Key Consideration	Yes/No	Notes
Were there any process concerns raised during the CDP project? If so, briefly explain.	No	
Did the Standing Committee receive requests for reconsideration? If so, briefly explain.	No	
Did the Standing Committee overturn any of the Scientific Methods Panel's ratings of Scientific Acceptability? If so, state the measure and why the measure was overturned.	No	
If a recommended measure is a related and/or competing measure, was a rationale provided for the Standing Committee's recommendation? If not, briefly explain.	N/A	
Were any measurement gap areas addressed? If so, identify the areas.	No	
Are there additional concerns that require CSAC discussion? If so, briefly explain.	No	

Appendix B: Measures Not Recommended for Endorsement

There were no Renal measures that were not recommended for endorsement.

Appendix C: NQF Member Expression of Support Results

No member expressions of support were received.

Appendix D: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Track 2 – Measures Recommended

2979 Standardized Transfusion Ratio for Dialysis Facilities

Submission

Description: The risk adjusted facility level transfusion ratio "STrR" is specified for all adult dialysis patients. It is a ratio of the number of eligible red blood cell 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.

This measure is calculated as a ratio, but can also be expressed as a rate.

Numerator Statement: Number of eligible observed red blood cell transfusion events: An event is defined as the transfer of one or more units of blood or blood products into a 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.

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.

Exclusions: All transfusions associated with transplant hospitalization are excluded. Patients are also 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 time at risk. 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 these exclusion eligible diagnoses.

Adjustment/Stratification: Statistical risk model N/A

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 01/30/2020

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Pass-16; No Pass-2**; 1b. Performance Gap: **H-1**; **M-13**; **L-2**; **I-1**

Rationale:

- Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g., ESA, iron).
- Dialysis patients who are eligible for kidney transplant and are transfused risk becoming sensitized to the donor pool, reducing the chances of transplant success. 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 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 FDA guidance regarding minimizing the use of ESAs, and economic incentives to

2979 Standardized Transfusion Ratio for Dialysis Facilities

minimize ESA use introduced by Medicare's bundling of payment for ESAs. As providers use fewer ESAs in an effort to minimize the risks associated with aggressive anemia treatment, it becomes more important to monitor for an overreliance on transfusions.
- The Committee noted that the evidence provided came from historical and observational studies, but concluded the evidence was reasonable to support the basis of the measure.
- The developer provided data from 2017 demonstrating a mean STrR of 1.058 with a range of 0.273 (10th percentile) to 1.306 (90th percentile). Parameter estimates provided for race, sex, and ethnicity indicated relatively little variation and no disparities substantial to the measure among these groups.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-13**; **L-2**; **I-1**; 2b. Validity: **H-1**; **M-10**; **L-3**; **I-2**

Rationale:

- This measure was deemed as complex and was evaluated by the NQF Scientific Methods Panel (SMP).
- The developer provided an overview of changes made to the measure specifications since the measure's previous endorsement: The developer added revenue codes to the inpatient transfusion definition to capture more inpatient transfusion events, and the measure now excludes Medicare Advantage patients due to incomplete claims data. Without full claims data, the developer stated it is impossible to accurately risk-adjust the measure results or capture of transfusion events, and exclusions would be incomplete, threatening the validity of the measure.
- The developer tested score-level reliability at the facility level using bootstrapping to evaluate inter-unit reliability (IUR). They found IURs for the one-year STrR have a range of 0.63-0.68 across the years 2014, 2015, 2016, and 2017. The developer interpreted these results as indicating a moderate level of reliability.
- The developer provided face validity assessment using a technical expert panel. The developer conducted score-level empirical testing using a Poisson regression model. The developer indicated significant association of the STrR with hospitalization, mortality, and percent of patients with low hemoglobin levels.
- The Committee noted that removal of Medicare Advantage patients from the denominator resulted in more patients being excluded from the measure.
- The Committee discussed the reliability and validity of the measure, and the changes to the specifications since the previous endorsement. The Committee determined their discussion warranted a Committee vote on both reliability and validity instead of accepting the SMP voting results.

3. Feasibility: H-11; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

Rationale:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected, and used by healthcare personnel during provision of care.

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-14; No Pass-2** *4b. Usability:* **H-3; M-11; L-1; I-0**

Rationale:

- This measure is publicly reported nationally on Dialysis Facility Compare (DFC) and is used in the ESRD QIP.
- The developer showed modeling results that demonstrated small but significant reductions in inpatient transfusion events for the years 2016-2017 compared with 2014-2015.
- During the December 2019 meeting of the Measure Applications Partnership (MAP) Hospital Workgroup, MAP considered this revised measure for inclusion in the ESRD QIP. MAP conditionally

2979 Standardized Transfusion Ratio for Dialysis Facilities
supported including the measure in ESRD QIP pending NQF endorsement of the revised measure. MAP noted that in 2021, Medicare Advantage will include dialysis that may impact the patient population captured by this measure • The developer indicated that it had not received any feedback indicating any unintended impacts on patients as a result of measure implementation.
5. Related and Competing Measures • No related or competing measures noted.
6. Standing Committee Recommendation for Endorsement: **Y-14**; **N-1**
7. Public and Member Comment • The commenter highlighted concerns associated with attribution. They noted that the dialysis facilities lack adequate information to determine if transfusions occurred at the hospital. • The comment also noted that while dialysis facilities can influence anemia, other measures may be more appropriate to capture this. • The comment called into question the reliability of the measure, especially for smaller facilities.
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
9. Appeals

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Renal
Fall 2019 Review Cycle

CSAC Review and Endorsement

November 17, 2020

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Standing Committee Recommendations

- One measure reviewed for Fall 2019 Track 2
  - One measure reviewed by the Scientific Methods Panel
- One measure recommended for endorsement
  - **NQF 2979** Standardized Transfusion Ratio for Dialysis Facilities (Maintenance Measure)

Public and Member Comment and Member Expressions of Support

- One comment received
  - Concern that measure reflects transfusion practices at the hospital level rather than dialysis facilities.
  - Concern that it is difficult for facilities to influence whether a patient receives a transfusion because they occur in hospitals.
  - Concern that 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 quality improvement efforts to significantly improve clinical care and outcomes.
  - Suggests there are more meaningful measures that would provide a more accurate picture of anemia management of patients on dialysis.
- These concerns and the developer's responses were reviewed and discussed by the Committee during the post comment call.
- No NQF member of expressions of support or non-support received

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Questions?

- Project team:
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Renal, Fall 2019 Cycle Track 2: CDP Report

DRAFT REPORT FOR CSAC REVIEW
NOVEMBER 17, 2020

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Contents

Executive Summary

Renal disease is a leading cause of morbidity and mortality in the United States. More than 36 million adults—representing more than 14 percent of the adult population—have chronic kidney disease (CKD).[1] Untreated, CKD can progress to an advanced state of kidney dysfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia, and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

Quality measurement plays a central role in facilitating improvement in the quality of care received by CKD patients, especially those on hemodialysis. NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare and Medicaid Services (CMS), such as the ESRD Quality Incentive Program (ESRD QIP).

This project sought to identify and endorse performance measures for accountability and quality improvement that address conditions, treatments, interventions, or procedures relating to kidney disease.

For this project, the Standing Committee evaluated one measure undergoing maintenance review against NQF's standard evaluation criteria. The Committee recommended one measure for endorsement:

- **NQF 2979** Standardized Transfusion Ratio for Dialysis Facilities

Due to circumstances around the COVID-19 global pandemic, commenting periods for all measures evaluated in the fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks:

Track 1: measures that remained in fall 2019 Cycle:

- None of the measures in the Renal fall 2019 cycle met the criteria for a track 1 measure.

Track 2: measures deferred to spring 2020 Cycle:

- **NQF 2979** Standardized Transfusion Ratio for Dialysis Facilities

This report contains details of the evaluation of measures assigned to *Track 2* and moved to the spring 2020 cycle. Detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Kidney disease has long been a leading cause of morbidity and mortality in the U.S. More than 36 million adults—representing more than 14 percent of the adult population—have chronic kidney disease (CKD).[1] Untreated, CKD can progress to an advanced state of kidney dysfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

In 1972, President Richard Nixon signed section 2991 of Public Law 92-603, which established ESRD as the only healthcare condition that Medicare covers for people under the age of 65.[2] Under this provision, people are eligible for Medicare regardless of their age if their kidneys are no longer functioning, if they need regular dialysis, or if they have had a kidney transplant. The United States continues to spend significant resources on care and treatment of CKD and ESRD. In 2010, total Medicare spending rose 6.5 percent, to $522.8 billion, and expenditures for ESRD rose 8 percent, to $32.9 billion.[1]

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (Appendix C) oversees NQF's portfolio of Renal measures (Appendix B). This portfolio contains 23 measures: six process measures, 13 intermediate outcome measures, and four outcome and resource use measures (see table below).

Table 1. NQF Renal Portfolio of Measures

	Process	Intermediate Outcome	Outcome
Hemodialysis	1	2	0
Hemodialysis - Pediatric	0	1	0
Hemodialysis Vascular Access	1	4	0
Dialysis Monitoring	1	1	0
Dialysis Monitoring - Pediatric	2	1	0
Peritoneal Dialysis	0	4	0
Patient Safety	0	0	4
Treatment Initiation	1	0	0
Total	6	13	4

The remaining measures have been assigned to other portfolios. These include various diabetes assessment and screening measures (Primary Care & Chronic Illness Standing Committee), eye care measures (Primary Care & Chronic Illness Standing Committee), ACEI/ARB medication measures (Cardiovascular and Primary Care & Chronic Illness Standing Committee), complications and outcomes measures (Cardiovascular, Patient Experience & Function, and Surgery Standing Committees), and cost and resource use measures (Cost and Efficiency project).

Renal Measure Evaluation

On January 30, 2020 the Renal Standing Committee evaluated one measure undergoing maintenance review against NQF's standard measure evaluation criteria.

Table 2. Renal Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	1	0	1
Measures recommended for endorsement	1	0	1

Comments Received Prior to Committee Evaluation

NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on November 26, 2019 and closed on April 09, 2020. No comments were submitted prior to the measure evaluation meetings.

Comments Received After Committee Evaluation

Considering the recent COVID-19 global pandemic, many organizations needed to focus their attention on the public health crisis. In order to provide greater flexibility for stakeholders and continue the important work in quality measurement, the National Quality Forum (NQF) extended commenting periods and adjusted measure endorsement timelines for the fall 2019 cycle.

Commenting periods for all measures evaluated in the fall 2019 cycle were extended from 30 days to 60 days. Based on the comments received during this 60-day extended commenting period, measures entered one of two tracks:

Track 1: Measures Remained in Fall 2019 Cycle
Measures that did not receive public comments or only received comments in support of the Standing Committees' recommendations moved forward to the CSAC for review and discussion during its meeting on July 28-29, 2020.

- **Exceptions**
  Exceptions were granted to measures if non-supportive comments received during the extended post-comment period were similar to those received during the pre-evaluation meeting period and have already been adjudicated by the respective Standing Committees during the measure evaluation fall 2019 meetings.

Track 2: Measures Deferred to Spring 2020 Cycle
Fall 2019 measures that required further action or discussion from a Standing Committee were deferred to the spring 2020 cycle. This includes measures where consensus was not reached or those that require a response to public comments received. Measures undergoing maintenance review retained endorsement during that time.

During the spring 2020 Consensus Standards Approval Committee (CSAC) meeting on November 17-18, 2020, the CSAC will review all measures assigned to Track 2.

The extended public commenting period with NQF member support closed on May 14, 2020. Following the Committee's evaluation of the measures under consideration, NQF received one comment from one member organization pertaining to the draft report and to the measure under consideration. All comments for each measure under consideration have been summarized in Appendix A.

Throughout the extended public commenting period, NQF members had the opportunity to express their support ('support' or 'do not support') for each measure submitted for endorsement consideration to inform the Committee's recommendations. No NQF members provided their expression of support or not support.

Summary of Measure Evaluation: Fall 2019 Measures, Track 2

The following brief summaries of the measure evaluation highlight the major issues that the Committee considered. Details of the Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

2979 Standardized Transfusion Ratio for Dialysis Facilities (University of Michigan Kidney Epidemiology and Cost Center): Recommended for Endorsement

Description: The risk-adjusted facility level transfusion ratio "STrR" is specified for all adult dialysis patients. It is a ratio of the number of eligible red blood cell 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.This measure is calculated as a ratio, but can also be expressed as a rate. **Measure Type**: Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

This outcome measure calculates a ratio of the number of eligible red blood cell 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. The Renal Standing Committee noted that the evidence was reasonable to support the basis of the measure, and the performance gaps demonstrated in the analysis submitted were sufficient to warrant continued endorsement of this measure. The developer provided an overview of changes made to the measure specifications since the measure's previous endorsement. To address concerns about under-identification of inpatient blood transfusions using International Classification of Diseases (ICD)-10 procedure codes, the developer added revenue codes to the inpatient transfusion definition. The developer presented data demonstrating that the broader definition captures more inpatient transfusion events than were previously captured. The developer also clarified that the measure excludes Medicare Advantage patients due to incomplete claims data. Both the Committee and the developer were concerned about excluding this group of patients, as Medicare Advantage patients have been increasingly represented in the population of patients receiving dialysis. Without full claims data, the developer stated it is impossible to accurately risk-adjust the measure results or the capture of

transfusion events and exclusions would be incomplete, threatening the validity of the measure. The Committee discussed the reliability and validity of the measure, and the changes to the specifications since the previous endorsement. The Committee determined their discussion warranted a Committee vote on both reliability and validity, and ultimately the Committee was satisfied that the measure met both criteria. The Committee did not express any concerns about the feasibility, use, and usability of the measure.

Measures Withdrawn from Consideration

One measure previously endorsed by NQF has been withdrawn during the endorsement evaluation process. Endorsement for this measure will be removed.

Table 3. Measures Withdrawn from Consideration

Measure	Reason for withdrawal
0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	Developer is not seeking re-endorsement.

References

1 U.S. Renal Data System (USRDS). 2018 Annual Data Report: Epidemiology of Kidney Disease in theUnited States. Bethesda, M.

2 CROWNWeb. CROWNWeb: History, Purpose, and Usage [video]. http://mycrownweb.org/help/about-crownweb/. Last accessed Decem.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Track 2 – Measures Recommended

2979 Standardized Transfusion Ratio for Dialysis Facilities

Submission | Specifications

Description: The risk adjusted facility level transfusion ratio "STrR" is specified for all adult dialysis patients. It is a ratio of the number of eligible red blood cell 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.

This measure is calculated as a ratio, but can also be expressed as a rate.

Numerator Statement: Number of eligible observed red blood cell transfusion events: An event is defined as the transfer of one or more units of blood or blood products into a 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.

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.

Exclusions: All transfusions associated with transplant hospitalization are excluded. Patients are also 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 time at risk. 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 these exclusion eligible diagnoses.

Adjustment/Stratification: Statistical risk model N/A

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 01/30/2020

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **Pass-16; No Pass-2**; 1b. Performance Gap: **H-1**; **M-13**; **L-2**; **I-1**

Rationale:

- Blood transfusion may be an indicator for underutilization of treatments to increase endogenous red blood cell production (e.g., ESA, iron).
- Dialysis patients who are eligible for kidney transplant and are transfused risk becoming sensitized to the donor pool, reducing the chances of transplant success. 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.

2979 Standardized Transfusion Ratio for Dialysis Facilities

- Monitoring the risk-adjusted transfusion rate at the 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 FDA guidance regarding minimizing the use of ESAs, and economic incentives to minimize ESA use introduced by Medicare's bundling of payment for ESAs. As providers use fewer ESAs in an effort to minimize the risks associated with aggressive anemia treatment, it becomes more important to monitor for an overreliance on transfusions.
- The Committee noted that the evidence provided came from historical and observational studies, but concluded the evidence was reasonable to support the basis of the measure.
- The developer provided data from 2017 demonstrating a mean STrR of 1.058 with a range of 0.273 (10th percentile) to 1.306 (90th percentile). Parameter estimates provided for race, sex, and ethnicity indicated relatively little variation and no disparities substantial to the measure among these groups.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-0**; **M-13**; **L-2**; **I-1**; 2b. Validity: **H-1**; **M-10**; **L-3**; **I-2**

<u>Rationale</u>:

- This measure was deemed as complex and was evaluated by the NQF Scientific Methods Panel (SMP).
- The developer provided an overview of changes made to the measure specifications since the measure's previous endorsement: The developer added revenue codes to the inpatient transfusion definition to capture more inpatient transfusion events, and the measure now excludes Medicare Advantage patients due to incomplete claims data. Without full claims data, the developer stated it is impossible to accurately risk-adjust the measure results or capture of transfusion events, and exclusions would be incomplete, threatening the validity of the measure.
- The developer tested score-level reliability at the facility level using bootstrapping to evaluate inter-unit reliability (IUR). They found IURs for the one-year STrR have a range of 0.63-0.68 across the years 2014, 2015, 2016, and 2017. The developer interpreted these results as indicating a moderate level of reliability.
- The developer provided face validity assessment using a technical expert panel. The developer conducted score-level empirical testing using a Poisson regression model. The developer indicated significant association of the STrR with hospitalization, mortality, and percent of patients with low hemoglobin levels.
- The Committee noted that removal of Medicare Advantage patients from the denominator resulted in more patients being excluded from the measure.
- The Committee discussed the reliability and validity of the measure, and the changes to the specifications since the previous endorsement. The Committee determined their discussion warranted a Committee vote on both reliability and validity instead of accepting the SMP voting results.

3. Feasibility: H-11; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c. Susceptibility to inaccuracies/ unintended consequences identified; 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected, and used by healthcare personnel during provision of care.
-

4. Use and Usability

4a. Use; 4a1. Accountability and transparency; 4a2. Feedback on the measure by those being measured and others; 4b. Usability; 4b1. Improvement; 4b2. The benefits to patients outweigh evidence of unintended negative consequences to patients)

4a. Use: **Pass-14; No Pass-2** *4b. Usability:* **H-3; M-11; L-1; I-0**

<u>Rationale</u>:

2979 Standardized Transfusion Ratio for Dialysis Facilities
• This measure is publicly reported nationally on Dialysis Facility Compare (DFC) and is used in the ESRD QIP. • The developer showed modeling results that demonstrated small but significant reductions in inpatient transfusion events for the years 2016-2017 compared with 2014-2015. • During the December 2019 meeting of the Measure Applications Partnership (MAP) Hospital Workgroup, MAP considered this revised measure for inclusion in the ESRD QIP. MAP conditionally supported including the measure in ESRD QIP pending NQF endorsement of the revised measure. MAP noted that in 2021, Medicare Advantage will include dialysis that may impact the patient population captured by this measure • The developer indicated that it had not received any feedback indicating any unintended impacts on patients as a result of measure implementation.
5. Related and Competing Measures • No related or competing measures noted.
6. Standing Committee Recommendation for Endorsement: **Y-14**; **N-1**
7. Public and Member Comment • The commenter highlighted concerns associated with attribution. They noted that the dialysis facilities lack adequate information to determine if transfusions occurred at the hospital. • The comment also noted that while dialysis facilities can influence anemia, other measures may be more appropriate to capture this. • The comment called into question the reliability of the measure, especially for smaller facilities.
8. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X
9. Appeals

Appendix B: Renal Portfolio—Use in Federal Programs[a]

NQF #	Title	Federal Programs
0255	Measurement of Phosphorus Concentration	End-Stage Renal Disease Quality Incentive Program
0256	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access	End-Stage Renal Disease Quality Incentive Program
0257	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	End-Stage Renal Disease Quality Incentive Program
0258	CAHPS In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration	End-Stage Renal Disease Quality Incentive Program
0260	Assessment of Health-related Quality of Life (Physical & Mental Functioning)	End-Stage Renal Disease Quality Incentive Program
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	End-Stage Renal Disease Quality Incentive Program
0369	Dialysis Facility Risk-adjusted Standardized Mortality Ratio	End-Stage Renal Disease Quality Incentive Program
0420	Pain Assessment and Follow-Up	End-Stage Renal Disease Quality Incentive Program
1463	Standardized Hospitalization Ratio for Admissions	End-Stage Renal Disease Quality Incentive Program
1667	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	Merit-Based Incentive Payment System (MIPS)
2706	Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V	End-Stage Renal Disease Quality Incentive Program
2977	Hemodialysis Vascular Access: Standardized Fistula Rate	End-Stage Renal Disease Quality Incentive Program
2978	Hemodialysis Vascular Access: Long-term Catheter Rate	End-Stage Renal Disease Quality Incentive Program
2979	Standardized Transfusion Ratio for Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program

[a] Per CMS Measures Inventory Tool as of 09/02/2020

Appendix C: Renal Standing Committee and NQF Staff

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Appendix D: Measure Specifications

	NQF 2979 Standardized Transfusion Ratio for Dialysis Facilities
Steward	Centers for Medicare & Medicaid Services
Description	The risk-adjusted facility level transfusion ratio "STrR" is specified for all adult dialysis patients. It is a ratio of the number of eligible red blood cell 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. This measure is calculated as a ratio, but can also be expressed as a rate.
Type	Outcome
Data Source	Claims, Registry Data Data are derived from an extensive national ESRD patient database, which is primarily based on the CMS Consolidated Renal Operations in a Web-enabled Network (CROWN) system. The CROWN data include the Renal Management Information System (REMIS), CROWNWeb facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form data), the historical Standard Information Management System (SIMS) database (formerly maintained by the 18 ESRD Networks until replaced by CROWNWeb in May 2012), the National Vascular Access Improvement Initiative's Fistula First Catheter Last project (in CROWNWeb since May 2012), Medicare dialysis and hospital payment records, transplant data from the Organ Procurement and Transplant Network (OPTN), the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Workbench, which includes data from the Certification and Survey Provider Enhanced Report System (CASPER), the Dialysis Facility Compare (DFC) and the Social Security Death Master File. The database is comprehensive for Medicare patients. Non-Medicare patients are included in all sources except for the Medicare payment records. CROWNWeb provides tracking by dialysis provider and treatment modality for non-Medicare patients. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity is obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims) and Part B outpatient types of Medicare Claims SAFs. Information on transfusions is obtained from Medicare Inpatient and Outpatient Claims Standard Analysis Files (SAFs).
Level	Facility
Setting	Other Dialysis Facility
Numerator Statement	Number of eligible observed red blood cell transfusion events: An event is defined as the transfer of one or more units of blood or blood products into a 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.
Numerator Details	Transfusion events in the inpatient setting are counted in the following way. The event is identified by presence in a Medicare inpatient claim of the appropriate ICD procedure codes (99.03, 99.04, 30230H1, 30233H1, 30240H1, 30243H1, 30250H1, 30253H1, 30260H1, 30263H1, 30230N1, 30230P1, 30233N1, 30233P1, 30240N1, 30240P1, 30243N1, 30243P1, 30250N1, 30250P1, 30253N1, 30253P1, 30260N1, 30260P1, 30263N1, 30263P1), or revenue center codes (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code (37). We only count a single transfusion event for an inpatient claim regardless of the number of transfusion revenue center, procedure 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

	NQF 2979 Standardized Transfusion Ratio for Dialysis Facilities
	units of blood. This results in a more conservative estimate of blood transfusions from inpatient claims. Transfusion events are less common in the outpatient setting. Transfusion events in the outpatient setting are counted in the following way. Events derived from outpatient claims are identified by claims with HCPCS code (P9010, P9011, P9016, P9021, P9022, P9038, P9039, P9040, P9051, P9054, P9056, P9058, 36430) with revenue center codes in (0380, 0381, 0382, 0389, 0390, 0391, 0392, 0399) or value code (37). One or more transfusion-related HCPCS codes with at least one transfusion-related revenue center codes, or one or more transfusion-related value codes listed on an outpatient claim are counted as a single transfusion event regardless of the number of units of blood recorded. In other words, 3 units of blood would be counted as a single transfusion event. If there are more than one transfusion events identified from inpatient or outpatient claims in the same day, we only count one transfusion event per day. The detailed procedures to determine unique transfusion events at the claim level are presented in a flow chart in the Appendix (S.19. Calculation Algorithm/Measure Logic Diagram).
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.
Denominator Details	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 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 the facility given its 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.
Exclusions	All transfusions associated with transplant hospitalization are excluded. Patients are also 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 time at risk. 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 one year free of claims that contain these exclusion eligible diagnoses.
Exclusion details	We performed multivariate logistic regression demonstrating that a one-year look-back period for the exclusion comorbidities was more predictive of transfusion events compared to longer look back periods. The figure in the appendix describes the inclusion and exclusion period of a hypothetical patient. In the figure included in the exclusion section of the testing form (Sec. 2b2.1), 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 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 the figure). This 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 toward the facility's total transfusion event count because the presence of the exclusion comorbidity claims

	NQF 2979 Standardized Transfusion Ratio for Dialysis Facilities
	within the one-year look-back might have increased the risk of transfusion unrelated to dialysis facility anemia management practices. However, T2, which occurs in late 2011 and in Inclusion2 period, will be counted since there is greater than a one-year gap between this transfusion event and the last claim observed with the exclusion diagnosis.
Risk Adjustment	Statistical risk model
Stratification	N/A
Type Score	Ratio better quality = lower score
Algorithm	The numerator is the observed number of transfusion events for a facility and the 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. See flowchart for further detail (available in attached appendix). 139029| 122107
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Appendix E: Related and Competing Measures

No related or competing measures were identified.

Appendix F: Pre-Evaluation Comments

No pre-evaluation comments were received.

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