NQF-Endorsed Measures for Renal Conditions, 2015-2017

TECHNICAL REPORT

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NATIONAL QUALITY FORUM

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NQF-Endorsed Measures for Renal Conditions, 2015-2017

Executive Summary

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). Untreated CKD can result in end-stage renal disease (ESRD) and a host of other health complications. Currently, over half a million people in the United States have received a diagnosis of ESRD, the only chronic disease covered by Medicare for people under the age of 65. 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.

On June 28, 2016, the Renal Standing Committee evaluated three newly submitted measures and three measures undergoing maintenance review against NQF's standard evaluation criteria. Four measures were recommended for endorsement, and the Committee did not recommend two measures. During the post-comment call, the Committee reconsidered the two measures not recommended and altered their decision for one of the measures. The Standing Committee endorsed five measures:

- 0369 Standardized Mortality Ratio for Dialysis Facilities (CMS)
- 1463 Standardized Hospitalization Ratio for Dialysis Facilities (CMS)
- 2977 Hemodialysis Vascular Access: Standardized Fistula Rate (CMS)
- 2978 Hemodialysis Vascular Access: Long-term Catheter Rate (CMS)
- 2979 Standardized Transfusion Ratio for Dialysis Facilities (CMS)

The Committee did not endorse the following measure:

- 0260 Assessment of Health-related Quality of Life in Dialysis Patients (Witten and Associates, LLC/RAND Corporation)

Brief summaries of the measures are included in the body of the report; detailed summaries of the Committee's discussions and ratings on the criteria for each measure are in Appendix A.

Introduction

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). It is associated with premature mortality, decreased quality of life, and increased healthcare costs. Risk factors for CKD include cardiovascular disease, diabetes, hypertension, and obesity.[1] 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.

In 1972, President Richard Nixon signed section 2991 of Public Law 92-603, which established ESRD as the only healthcare condition to be covered under Medicare for people under the age of 65.[2] 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. 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. 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.[3]

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 June 28, 2016, NQF convened a multistakeholder Standing Committee composed of 23 individuals to evaluate three NQF-endorsed maintenance measures and three new measures and make recommendations for endorsement.

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (see Appendix D) oversees NQF's portfolio of 21 renal measures. There are additional measures that could be considered related to renal care but are designated as more appropriate for inclusion in other NQF projects. These include various diabetes assessment and screening measures, eye care measures, ACEI/ARB medication measures, complications and outcomes measures, cost and resource use measures.

The renal portfolio contains seven process measures and 14 outcome measures (see table below).

Table 1. NQF Renal Portfolio of Measures

	Process	Outcome/Resource Use
Dialysis Monitoring	3	2
Hemodialysis	1	3
Hemodialysis Vascular Access	1	2
Patient Safety	—	3
Peritoneal Dialysis	—	4
Other	2	—
Total	7	14

National Quality Strategy

NQF-endorsed measures for renal care support the National Quality Strategy (NQS). NQS serves as the overarching framework for guiding and aligning public and private efforts across all levels (local, state, and national) to improve the quality of healthcare in the U.S. The NQS establishes the "triple aim" of better care, affordable care, and healthy people/communities, focusing on six priorities to achieve those aims: *Safety, Person and Family Centered Care, Communication and Care Coordination, Effective Prevention and Treatment of Illness, Best Practices for Healthy Living,* and *Affordable Care.*

Quality measures for renal care align with several of the NQS priorities, including:

- Effective Prevention and Treatment of Illness
- Patient Safety
- Communication and Care Coordination

Use of Measures in the Portfolio

Endorsement of measures by NQF is valued because the evaluation process is both rigorous and transparent, and also because evaluations are conducted by multistakeholder committees composed of clinicians and other experts representing the healthcare spectrum, including healthcare providers, employers, health plans, public agencies, community coalitions, and patients—many of whom use measures on a daily basis to ensure better care. Moreover, NQF-endorsed measures undergo routine "maintenance" (i.e., re-evaluation) to ensure that they are still the best available measures and reflect the current science. Importantly, federal law requires that preference be given to NQF-endorsed measures for use in federal public reporting and performance-based payment programs.

The measures considered in this Renal Project are being implemented at various levels within the healthcare system. A few of the new measures are in use in internal quality improvement efforts or have been developed for consideration for use in federal programs in the future. Most of the measures under consideration for maintenance endorsement are in use in the CMS ESRD Quality Incentive Program (QIP) and are used for Dialysis Facility Compare. See Appendix C for details of federal program use for the measures in the portfolio that were reviewed in this project.

The Committee engaged in some discussion about how measure performance is represented when used in a program such as the ESRD QIP or five-star rating system. It was noted that some measures, such as the standardized ratios (hospitalization, transfusion, mortality, etc.) have relatively wide confidence intervals, raising the possibility that hospitals could be misclassified and assigned a grade or rating that does not truly reflect their performance. Committee members suggested that CMS should continue to examine these rating systems and work to improve their precision.

Improving NQF's Renal Portfolio

Committee Input on Gaps in the Portfolio

The Renal Committee discussed gaps in measurement related to dialysis and care for ESRD patients. Issues addressed by the Committee included the following.

Patient-Reported Outcomes

Committee members agreed that patient-reported outcomes (PROs) are an important focus of measurement for renal care, noting that the Patient-Reported Outcomes Measurement Information System (PROMIS) has developed measures in other areas and could help advance PRO measurement for renal care as well.

Patient Experience of Care and Engagement

Committee members suggested there is a need to work on defining and measuring patients' experience of care. This could help the dialysis care community understand why patients don't adhere to treatments or when patients have problems with their treatment. Committee members noted that patients may have different goals for their care, and should be provided the opportunity to decide what is important to them. It was noted that incorporating patient preferences, choices, and priorities into measurement is an important issue that can be considered distinct from measuring patient-centered outcomes. Committee members suggested that determining and pursuing patient preferences can also have a positive impact on staff and staff retention.

In addition, Committee members suggested that measures based on patient-reported information, such as depression screening, In-Center Hemodialysis Center (ICH) CAHPS, and the KDQOL survey, should have consistent inclusion and exclusion criteria to reduce confusion and improve harmonization.

Care for Comorbid Conditions

Committee members observed that ESRD patients frequently have comorbidities, including diabetes and cardiovascular disease, which have a significant impact on their health status and outcomes. Renal care therefore needs to be coordinated and aligned with care for these related conditions. Measurement should address harmonization of activities and effective, meaningful exchange of data across nephrologists, cardiologists, endocrinologists, and other providers. Committee members also suggested that understanding and addressing frailty in dialysis patients will be an important consideration for measurement.

Palliative Dialysis

Patients who have transitioned to palliative care can have limited access to dialysis. Committee members suggested that the renal community should explore ways to permit dialysis for palliative care patients within reasonable bounds (e.g., less than three times per week) to help these patients achieve quality-of-life goals and other informed care preferences. Some Committee members noted that it is also important to identify patients who should not start dialysis, and those who should transition to hospice care.

Vascular Access

While there are existing measures addressing vascular access for dialysis treatment, Committee members noted that gaps remain in this area. Committee members specifically raised the issue of patients getting repeated procedures to create arteriovenous fistulas; there is a need to improve the system's ability to identify instances where the usual approaches have failed or where patient

characteristics have an impact on vascular access, and to look at measuring outcomes in different ways for these patients.

Other Issues

Other issues addressed by Committee members included measurement of young dialysis patients' preparedness for transition from pediatric facilities to adult facilities, measuring rehabilitation of people who are working age, and the need to harmonize and improve approaches to measuring bloodstream infections across dialysis and other facilities.

Renal Measure Evaluation

On June 28, 2016, the Renal Standing Committee evaluated three new measures and three measures undergoing maintenance review against NQF's standard evaluation criteria. Four measures were recommended for endorsement, and the Committee did not recommend two measures. During the post-comment call, the Committee reconsidered the two measures not recommended and altered their decision for one of the measures. The Committee ultimately endorsed five measures (Table 2).

Table 2. Renal Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	3	3	6
Measures endorsed	2	3	5
Measures not endorsed	1	—	1
Reasons for not endorsing	Importance – 0 Scientific Acceptability – 1 Overall – 0 Competing Measure – 0	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – 0	

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 prior to the evaluation of measures via an online tool located on the project webpage. For this evaluation cycle, the pre-evaluation comment period was open from May 31 to June 13, 2016, for all six measures under review. A total of 29 pre-evaluation comments were received (Appendix G). All submitted comments were provided to the Committee prior to its initial deliberations during the in-person meeting.

Summary of Measure Evaluation

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 in included in Appendix A.

Endorsed Measures

0369 Standardized Mortality Ratio for Dialysis Facilities (Centers for Medicare & Medicaid Services): Endorsed

Description: Standardized mortality ratio for dialysis facility patients. 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**: Dialysis Facility; **Data Source**: Administrative claims, Electronic Clinical Data

This facility-level measure was originally endorsed in 2008 and maintained endorsement in 2012. The measure is publicly reported nationally in Dialysis Facility Compare (DFC). This measure calculates a standardized mortality ratio to assess how successful dialysis facilities are in avoiding mortality for their patients compared to expectations (based on the performance of similar facilities). The developer indicates that there are numerous dialysis care processes that can influence the likelihood of a patient dying. The reliability of the Standardized Mortality Ratio (SMR) was assessed using data among ESRD dialysis patients during 2010-2013. Inter-unit reliability (IUR) for the one-year SMR ranged from 0.26-0.32 across the years, which the developer admitted indicates a relatively low degree of reliability, suggesting that only 26 to 32 percent of variability in measure performance can be attributed to between-facility variation. While reliability improved when four-year data were used, the Committee found that the reliability was not strong enough to be a national standard and initially did not recommended NQF #0369 for maintenance of endorsement.

During the post-comment call, the Committee reviewed the comments received and the information provided by the developer. The Committee was satisfied with the additional information provided and decided to reconsider this measure. After discussing and voting on the reliability, validity, feasibility, and usability and use criteria, the Committee unanimously recommended the measure for endorsement.

1463 Standardized Hospitalization Ratio for Dialysis Facilities (Centers for Medicare & Medicaid Services): Endorsed

Description: Standardized hospitalization ratio for dialysis facility patients. 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**: Dialysis Facility; **Data Source**: Administrative claims, Electronic Clinical Data

This facility-level measure was originally endorsed in 2011. The measure is publicly reported nationally in Dialysis Facility Compare (DFC). The measure calculates a standardized hospitalization ratio to assess how successful dialysis facilities are in avoiding hospitalization for their patients compared to expectations (based on the performance of similar facilities). The measure can also be expressed as a rate. The Committee considered there to be a strong rationale for measuring this health outcome. Overall, the Committee agreed that the measure met the NQF criteria and recommended NQF #1463 for endorsement.

2977 Hemodialysis Vascular Access: Standardized Fistula Rate (Centers for Medicare & Medicaid Services): Endorsed

Description: Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access; **Measure Type**: Intermediate Clinical

Outcome; **Level of Analysis**: Facility; **Setting of Care**: Dialysis Facility; **Data Source**: Administrative claims, Electronic Clinical Data

This facility-level measure is newly submitted for endorsement. The measure is not yet implemented in a public reporting program, but, if it is endorsed, CMS expects to implement it as a replacement for an older fistula rate measure that is currently in use as part of the ESRD QIP and Dialysis Facility Compare programs. The Committee agreed that there is a definite association between type of vascular access used for hemodialysis and the risk of patient mortality. In addition, a systematic review of the evidence consistently demonstrates the reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis, and there continues to be opportunity for improvement in this area. While some Committee members expressed concerns about the developer's approach to exclusions, the Committee ultimately agreed that NQF #2977 met the NQF criteria and recommended it for endorsement.

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate (Centers for Medicare & Medicaid Services): Endorsed

Description: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access; **Measure Type**: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Dialysis Facility; **Data Source**: Administrative claims, Electronic Clinical Data

This facility-level measure was newly submitted for endorsement. Similar to measure #2977, if this measure is endorsed, CMS expects to implement it as a replacement for an older catheter rate measure that is currently in use as part of the ESRD QIP and Dialysis Facility Compare programs. While some Committee members noted that the evidence for this measure is retrospective and observational, and it may not capture information relevant to smaller subsets of the population, the Committee generally agreed that there is an association between the type of vascular access used for hemodialysis and patient mortality. The Committee expressed some concern that the measure does not account for length of time on dialysis or insurance status, which are factors that may have an impact on patients' ability to receive procedures to create arteriovenous fistulas. However, Committee members generally thought that the measure met the NQF criteria and recommended it for endorsement.

2979 Standardized Transfusion Ratio for Dialysis Facilities (Centers for Medicare & Medicaid Services): Endorsed

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**: Dialysis Facility; **Data Source**: Administrative claims, Electronic Clinical Data

NQF #2979 is an outcome measure specifed at the facility level and is newly submitted for endorsement. It measures the risk-adjusted transfusion rate at the dialysis facility level, allowing for detection of

treatment patterns in dialysis-related anemia management. This is of particular importance due to Food and Drug Administration (FDA) guidance regarding minimizing the use of erythropoiesis-stimulating agents (ESAs), and economic incentives to minimize ESA use introduced by Medicare's bundling of payment for ESAs. This measure is publicly reported nationally in Dialysis Facility Compare (DFC) and has been finalized for use in the End-Stage Renal Disease Quality Incentive Program starting FY2018. There was some discussion about the classification of this measure (i.e., whether it should be considered an outcome measure) as well as the appropriateness of exclusions and the measure's reliability. Measure testing showed fairly strong reliability in larger dialysis facilities and for the overall measure, but lower reliability was observed in smaller dialysis facilities. Noting that the overall reliability results were in line with other NQF-endorsed measures, the Committee determined that the measure was sufficiently reliable and that it met the criteria for endorsement.

Measures Not Endorsed

0260 Assessment of Health-Related Quality of Life in Dialysis Patients (Witten and Associates, LLC/RAND Corporation): Not Endorsed

Description: Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Dialysis Facility; **Data Source**: Patient Reported Data/Survey

NQF #0260 is a facility-level process measure that was originally endorsed in 2007. It measures the percentage of eligible dialysis patients who complete a health-related quality of life assessment using the KDQOL survey tool. The Committee found the evidence presented insufficient, but provided an exception to the evidence criterion, noting that while this is a process that is distant from patient outcomes, it is an important first step in assessing quality of life and patient outcomes. Measure data from 2015 reflecting 1,261 facilities show a median measure score of 91.8 percent. The Committee did not reach consensus on continued performance gap and noted that CMS requires dialysis facilities to assess patients' quality of life as part of the Conditions for Coverage. The Committee raised concerns about exclusions and the ability to reliably capture all of the exclusions that were introduced in the update of the measure; as a result of these concerns, the Committee did not reach consensus on the reliability criterion. In addition, they did not find the validity testing approach and conclusions from that testing to support of the measure. One area of specific concern was a potential need for case-mix adjustment or better understanding of differences in completion rates and how they affect measure performance across facilities. The Committee was unable to reach consensus on the reliability criterion and failed to pass the validity criterion. The measure was not recommended for endorsement.

The developer submitted a reconsideration request during the comment period. During the post-comment call, after reviewing the comment received and the information provided by the developer, the Committee upheld its decision to not recommend the measure for endorsement. The Committee expressed concerns with the lack of a performance gap and again expressed concerns with exclusions. It was also noted, that although the Committee did not recommend this specific process measure, it does support the need for assessment of renal patient quality of life and continues to support the notion of moving to patient-reported outcomes for this area.

References

[1] U.S. Renal Data System(USRDS). *USRDS 2010 Annual Data Report: Atlas of Chronic Kidney Disease and End-Stage Renal Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2010. Available at http://www.usrds.org/atlas.htm. Last accessed June 2016.

[2] CROWNWeb. CROWNWeb: History, Purpose, and Usage [video]. http://mycrownweb.org/help/what_is_crownweb/. Last accessed December 2015.

[3] U.S. Renal Data System (USRDS). *2014 Annual Data Report: Epidemiology of Kidney Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2014. Available at http://www.usrds.org/atlas.htm. Last accessed January 2017.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable; **Y**=Yes; **N**=No

Endorsed Measures

0369 Standardized Mortality Ratio for Dialysis Facilities

Submission | Specifications

Description: Standardized mortality ratio for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

Numerator Statement: Number of deaths among eligible patients at the facility during the time period.

Denominator Statement: Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.

Exclusions: N/A

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **Y-17; N-2**; 1b. Performance Gap: **H-5; M-13; L-0; I-1**

Rationale:

- The Committee agreed with the developer that there are numerous dialysis care processes that can influence the likelihood of a patient's dying. These processes include:
    - Fluid management/removal. Inadequate control of total body fluid balance and fluid removal can result in fluid overload and congestive heart failure, increasing the possibility of death.
    - Infection prevention. Inadequate infection prevention processes, including suboptimal management of vascular access, can lead to bacteremia or septicemia, increasing the possibility of death.
    - Dialysis. Failure to maintain processes to ensure adequate dialysis can lead to low Kt/v, increasing the possibility of death.
- The Committee concluded that there was enough of a gap in care to warrant a national performance measure. For the period 2010 – 2013, the 4 year SMR varied from 0.00 to 3.1. The mean value for 4-year SMR was 1.02 and the standard deviation was 0.28.

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-1; M-3; L-14; I-1;** 2a. Reliability Revote: **H-2; M-14; L-0; I-0;** 2b. Validity: **H-2; M-14; L-0; I-0**

<u>Rationale</u>:

- The Committee agreed that the developer's changes to the measure were appropriate. The following updates were made since the last submission:
    - The model adjusts for each incident comorbidity separately rather than using a comorbidity index.
    - The indicators for diabetes were modified by consolidating the individual indicators.
    - Adjustments for 210 prevalent comorbidities (identified through Medicare claims) were included
    - The measure is now limited to Medicare patients.
- However, initially, the Committee did not agree that the measure could be reliably implemented. The reliability of the Standardized Mortality Ratio (SMR) was assessed using data among ESRD dialysis patients during 2010-2013. IURs for the one-year SMR ranged from 0.26-0.32 across the years, which the developer admitted indicates a relatively low degree of reliability.
- The developer found that reliability improved when four-year data were used, with the IUR for the four-year SMR for 2010-2013 being 0.59. However, the Committee did not find this level of reliability to be strong enough for a national standard.
- The Committee suggested that the analysis seemed over-modeled and noted that the developer might consider reducing the included prevalent comorbidities in order to improve reliability. They also recommended that the measure should be reported as a rate instead of a ratio to help patients better understand the information they are being provided.
- During the comment period, the developer submitted a request for reconsideration of the measure. After reviewing revised testing based on a four-year SMR provided by the developer, the Committee decided to reconsider the measure and determined the reliability results were acceptable.
- To empirically assess validity, the SMR was compared to other quality of care indicators, including the Standardized Hospitalization Ratio (SHR) – Admissions, the Standardized Readmission Ratio (SRR), the Standardized Transfusion Ratio (STrR), percent of patients dialyzing with a fistula, percent of patients dialyzing with a catheter, and percent of patients with Kt/V >=1.2 to determine validity. Because the correlations were approximately the same for the four years 2010-2013, the developer only reported the 2013 correlations.
- Face validity was assessed by a TEP in 2006 for potential implementation on Dialysis Facility Compare (DFC). In 2015, a TEP was held specifically to consider prevalent comorbidity adjustments for inclusion in the measure. The TEP's recommendations are reflected in the risk adjustment methodology.
- The Committee agreed with the developer that the results indicated higher standardized mortality rates in facilities are associated with higher standardized hospitalization rates, higher standardized readmissions rates and higher standardized transfusion rates, higher values of SMR are associated with increased use of catheters and lower SMRs are associated with a higher percentage of patients receiving adequate dialysis dose.

3. Feasibility: H-13; M-4; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The Committee agreed all data elements are in defined fields in electronic form and generated or collected by and used by healthcare personnel during the provision of care.

4. Usability and Use: H-17; M-0; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is publically reported nationally in Dialysis Facility Compare (DFC).
- The developer states that mortality rates have decreased over time as evidenced by the coefficients for calendar year from the SMR model. The mortality rate for 2011 was 2.6% lower compared to 2010 (p-value<0.0001), and the rates for 2012 and 2013 were lower compared to 2010 at 12.4% and 13.0%, respectively (p-value <0.0001).

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17; N-0**

6. Public and Member Comment

- One Commenter supported the Committee's decision to not endorse the measure and one commenter felt the measure should have been recommended for endorsement.
- The Committee reviewed the comments received and the information provided by the developer. The Committee was satisfied with the additional information provided and decided to reconsider this measure. After discussing and voting on the reliability, validity, feasibility and usability and use criteria, the Committee unanimously recommended the measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote (November 2, 2016): Y-17; N-0

CSAC Decision: Approved for continued endorsement

8. Board of Directors Vote (November 21, 2016): Yes

Board Decision: Ratified for continued endorsement

9. Appeals

No appeals received.

1463 Standardized Hospitalization Ratio for Dialysis Facilities

Submission | Specifications

Description: Standardized hospitalization ratio for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

Numerator Statement: Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.

Denominator Statement: Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.

Exclusions: None.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **Y-18; N-1;** 1b. Performance Gap: **H-7; M-12; L-0; I-0**

Rationale:

- The Committee agreed with the developer's rationale for measuring this health outcome:
  - Hospitalization rates remain very high in US chronic dialysis patients relative to the general population, despite a nearly 20% decline from 2005-2013.
  - According to the 2015 USRDS Annual Report, approximately ½ of all dialysis patient hospitalizations continue to be caused by cardiovascular or infectious causes.
  - Programs developed to impact dialysis provider practices have been shown to improve intermediate outcomes (reduced catheter vascular access, small solute adequacy, anemia management) and mortality, modality options, infection prevention, and dialysis organization culture. These practice improvements have been linked to reduced hospitalizations in this population.
- The Committee concluded there was a gap in care that warranted a national performance measure. For 2014, the Standardized Hospitalization Ratio (SHR) varied from 0.07 to 2.92. The mean value was 0.99 and the Standard Deviation (or error) was 0.27.

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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-5; M-13; L-1; I-0;** 2b. Validity: **H-6; M-13; L-0; I-0**

Rationale:

- Inter-unit reliability for the one-year SHRs have a range of 0.70-0.72 for Medicare ESRD dialysis patients across the years 2010, 2011, 2012 and 2013, which the Committee agreed indicated the measure could be reliably implemented.
- The Committee concluded the measure was strengthened by updated empirical validity testing of the measure score with 2010-2013 data and new face validity conducted with a TEP in 2015. The SHR correlates with outcomes, processes of care, and causes of hospitalization that are commonly thought to be potentially related to poor quality of care. Higher rates of hospitalization were associated with higher facility mortality and readmission rates. The developer found higher values of SHR are associated with lower usage of AV Fistulas, higher catheter use, and suboptimal dialysis adequacy.

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3. Feasibility: H-14; M-5; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The Committee agreed all data elements are in defined fields in electronic form and generated or collected by and used by healthcare personnel during the provision of care.

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4. Usability and Use: H-8; M-11; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is publically reported nationally in Dialysis Facility Compare (DFC).
- The developer states that, as measured by the SHR, hospitalization rates have decreased over time. Compared to 2010, the hospitalization rate was 3% lower for 2011 (p-value <0.0001), 12.7% lower for 2012, and about 16.2% lower for 2013 (p-value<0.0001 for both).

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-19; N-0**

6. Public and Member Comment

- One commenter, the Kidney Care Partners, believes hospitalization is an important outcome to measure, but has concerns about the specifications, reliability, validity (risk model), and harmonization issues. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which demonstrate significant reliability issues with the one-year SHR for small facilities, and comment specifically on the SHR's reliability for such facilities.
- The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person and maintained that the measure meets the NQF criteria.

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7. Consensus Standards Approval Committee (CSAC) Vote (November 2, 2016): Y-19; N-0

CSAC Decision: Approved for continued endorsement

8. Board of Directors Vote (November 21, 2016): Yes

Board Decision: Ratified for continued endorsement

9. Appeals

No appeals received.

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

Submission | Specifications

Description: Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

Numerator Statement: The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.

Denominator Statement: All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the entire reporting month at the same facility.

Exclusions: Exclusions that are implicit in the denominator definition include:

- Pediatric patients (<18 years old)
- Patients on Peritoneal Dialysis
- Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

- Patients under hospice care in the current reporting month
- Patients with metastatic cancer in the past 12 months
- Patients with end stage liver disease in the past 12 months
- Patients with coma or anoxic brain injury in the past 12 months

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **H-5; M-14; L-0; I-0;** 1b. Performance Gap: **H-10; M-8; L-1; I-0**

Rationale:

- The Committee agreed that there is sufficient evidence for measuring this intermediate outcome:
    - There is a definite association between type of vascular access used for hemodialysis and the risk of patient mortality.
    - The developer provided results of a systematic review of the evidence, concluding that a number of epidemiologic studies consistently demonstrate reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.
    - The measure is intended to be jointly reported with Hemodialysis Vascular Access: Long-term Catheter Rate. Used together, the two vascular access quality measures consider Arterial Venous Fistula (AVF) use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome.
- Committee members agreed with the developer's rationale for the gap in performance and disparities is significant. The developer notes that interquartile differences in measure performance from CROWNWeb show substantial disparities across a variety of demographic categories.

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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-4; M-15; L-0; I-0;** 2b. Validity: **H-6; M-13; L-0; I-0**

Rationale:

- The Committee agreed that the developer's testing results showed sufficient reliability, with an inter-unit reliability analysis showing that about 74 percent of variation in measure scores could be attributable to true differences in performance scores between facilities.
- Validity was tested by assessing the degree to which scores on this measure were correlated with scores on the Standardized Mortality Ratio and Standardized Hospitalization Ratio.
- This analysis showed that Standardized Fistula Rates had a significantly negative association with risks of mortality and hospitalization.
- Some Committee members suggested that the exclusions needed to be defined more specifically (e.g., using specific codes); it was also noted that the rate of exclusions seemed to be low.
- The Committee also expressed concern that exclusions can only be applied to Medicare patients. The developer noted that their analyses showed that facilities' proportion of Medicare patients did not impact performance scores, suggesting there is minimal risk of bias.

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3. Feasibility: H-16; M-3; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- Members of the Committee agreed that the data is feasible to collect and most has already been collected. The Committee also agreed that the data elements are generated as part of the care delivery process.

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4. Usability and Use: H-7; M-12; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- The Developer stated that, upon endorsement, CMS will consider retiring the currently-endorsed measure of fistula use (#0257) in favor of this new measure for implementation in the End Stage Renal Disease Quality Improvement Program (ESRD QIP) and Dialysis Facility Compare in future performance years.
- Though the measure is not yet implemented in a public reporting program, CMS expects implementation of the standardized fistula rate measure.
- The Committee had concerns that there may be subsets of patients other than those excluded for which fistula use is not as well correlated with poor outcomes. Additionally, patient choice is not considered, potentially causing pressure for patients to undergo multiple procedures to establish fistulae.

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5. Related and Competing Measures

- This measure is related to:
    - 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
    - 0256: Hemodialysis Vascular Access-Minimizing use of catheters as Chronic Dialysis Access
    - 0257: Hemodialysis Vascular Access-Maximizing Placement of Arterial Venous Fistula (AVF)
    - 2978: Hemodialysis Vascular Access: Long-term Catheter Rate
- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. The Committee determined these measures were related but did not need to be further harmonized.

Standing Committee Recommendation for Endorsement: **Y-19; N-0**

6. Public and Member Comment

- The Kidney Care Partners has recommended the developer consider the following modifications to improve the measure going forward:
    - Stating that the specifications for #2977 are too imprecise, suggest the numerator specifies the patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present." Additional, credit should be received for a patient who is using an AVF as the sole means of access, but who also may have a non-functioning AV graft present.

- Suggest that two additional vasculature risk variables that could strengthen the model be added: a history of multiple prior accesses and the presence of a cardiac device.
- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. The Committee determined these measures were related, however, agreed the developer was taking all necessary steps to harmonize.

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7. Consensus Standards Approval Committee (CSAC) Vote (November 2, 2016): Y-19; N-0

CSAC Decision: Approved for endorsement

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8. Board of Directors Vote (November 21, 2016): Yes

Board Decision: Ratified for endorsement

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9. Appeals

No appeals received.

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate

Submission | Specifications

Description: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

Numerator Statement: The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

Denominator Statement: All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

Exclusions: Exclusions that are implicit in the denominator definition include:

-Pediatric patients (<18 years old)

-Patients on Peritoneal Dialysis

-Patient-months under in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

-Patients under hospice care in the current reporting month

-Patients with metastatic cancer in the past 12 months

-Patients with end stage liver disease in the past 12 months

-Patients with coma or anoxic brain injury in the past 12 months

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **H-4; M-14; L-0; I-0;** 1b. Performance Gap: **H-4; M-14; L-0; I-0**

Rationale:

- The Committee agreed the evidence establishes the relationship between improved processes of care and health outcomes of interest in this population, but some Committee members suggested that, as a measure of long-term catheter usage in dialysis facilities, the measure may be more appropriately considered a process measure rather than an intermediate clinical outcome.
- The majority of evidence supporting this measure substantiates the importance of decreasing long-term catheter usage in the broader ESRD population, however, there are continued concerns about impact on subpopulations, such as the frail-elderly. The Committee encouraged the developer to continue to assess impact on special population groups.
- The Committee agreed with the developer that, in general, there is an association between the type of vascular access used for hemodialysis and patient mortality and passed the measure on evidence.
- The Committee noted that data provided by the developer show a decline in chronic catheter use over time. Disparities data showed a number of population groups were more likely to have catheters; these include women, older patients (75 years and older) and those patients who with an ESRD diagnosis for less than a year and those diagnosed for more than 9 years. White patients were less likely to have catheters.
- The Committee generally agreed that the data provided showed there was opportunity for improvement.
- Committee members discussed the developer's finding that 18-25 year olds have higher rates of catheter usage; some Committee members noted that this is also the population with the highest rate of intravenous drug usage, suggesting that surgeons' hesitance to operate on this population may be one reason for their higher rate of catheter usage.

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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-8; M-8; L-1; I-0;** 2b. Validity: **H-3; M-13; L-2; I-0**

Rationale:

- To demonstrate reliability, the developer calculated the inter-unit reliability (IUR) for annual performance scores on the measure. This analysis included facilities with at least 11 patients

during the entire year. The Committee agreed with the Developer's conclusion that an IUR of 0.765 (76.5%) suggests a high degree of reliability.

- The Developer provided clarification for Committee member concerns that missing fields and other unknown data were counted as catheters.
    - The developer suggested this was done to provide a strong incentive for providers and facilities to report access and make sure that records were kept up-to-date.
- The Committee members took issue with not taking vintage (length of time on dialysis) and insurance coverage into consideration, noting that these factors can contribute to very meaningful differences between certain facilities in any given area.
- The type of insurance a patient has and whether they are capitated to a group that will provide the service may have a significant impact on timely vascular access for that patient.
- The Committee requested the developer clarify information regarding insurance status, noting that many commercial entities are not participating in coverage under the Affordable Care Act (ACA). The developer suggested that the decision to not risk-adjust the measure was made to avoid giving facilities a pass on issues that may be in their control.

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3. Feasibility: H-14; M-4; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The Committee agreed that the data is feasible to collect and most has already been collected. Committee members also agreed that the data elements are generated as part of the care delivery process.

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4. Usability and Use: H-10; M-8; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- The developer stated that, upon endorsement, CMS will consider retiring the currently-endorsed measure of catheter use (#0256) in favor of this new measure for implementation in the End Stage Renal Disease Quality Improvement Program (ESRD QIP) and Dialysis Facility Compare in future performance years.

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5. Related and Competing Measures

- This measure is related to:
    - 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
    - 0256 - Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
    - 0257 - Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
    - 2977: Hemodialysis Vascular Access: Standardized Fistula Rate

- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. The Committee determined these measures were related, however, agreed the developer was taking all necessary steps to harmonize.

Standing Committee Recommendation for Endorsement: **Y-18; N-0**

6. Public and Member Comment

- Three commenters supported the Committee's recommendation to endorse the measure.

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7. Consensus Standards Approval Committee (CSAC) Vote (November 2, 2016): Y-18; N-0

CSAC Decision: Approved for endorsement

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8. Board of Directors Vote (November 21, 2016): Yes

Board Decision: Ratified for endorsement

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9. Appeals

No appeals received.

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

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **Y-18; N-2;** 1b. Performance Gap: **H-2; M-12; L-5; I-1**

Rationale:

- The Committee discussed whether or not this measure would be more appropriately categorized as an intermediate outcome. The Committee discussed how the use of scarce resources, particularly when comparing an event to a non-event--even if it is a relatively scarce event-- is considered an appropriate health outcome metric for the healthcare system, but not for the individual patient. The Committee proceeded to evaluate the measure as an outcome measure.
- The Committee passed the measure on evidence, agreeing that providers can take actions (e.g., utilization of treatments to increase blood cell production) to reduce the occurrence of transfusions.
- Committee members noted that dialysis patients who are eligible for kidney transplant and are transfused risk the development of becoming sensitized to the donor pool, thereby leading to potential negative consequences for kidney transplantation. Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to a national standard, allows for detection of treatment patterns in dialysis-related anemia management.
- Some Committee members noted they found the evidence to be most convincing in terms of negative downstream implications for a kidney transplant; others noted that downstream effects are difficult to know, as are the appropriate number of transplants in terms of cost and patient outcomes. Overall, the Committee agreed that the national standard of practice is transfusion avoidance.
- CROWNWeb and Medicare claims data for 2011-2014 showed that standardized transfusion ratios vary across facilities. Analyses of the standardized transfusion ratios (STrR) by race, sex and ethnicity indicate relatively little variation and no disparities substantial to the measure

among these groups. The Committee agreed that opportunity for improvement for performance of this measure remains moderate.

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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-15; L-5; I-0;** 2b. Validity: **H-0; M-15; L-5; I-0**

<u>Rationale</u>:

- Some Committee members had concerns about the specifications, specifically the lack of exclusion related to patients who may need transfusions due to acute gastrointestinal bleeds, trauma, or other unplanned surgery.
- Developers provided results of reliability testing of the performance measure score using Medicare claims data from 2011-2014 at the facility level of analysis. Inter-unit reliability (IUR) was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within-facility variation that cannot be directly estimated by a one-way analysis of variance. IURs had a range of 0.60-0.66 across the years 2011, 2012, 2013 and 2014, indicating that around two-thirds of the variation in the one-year STrR can be attributed to the between-facility differences and one-third to within-facility variation. Committee members noted that when stratified by facility size, the measure has higher IUR in larger dialysis facilities and lower IUR in smaller facilities. While some concern was expressed over the lower reliability for small facilities, the Committee generally agreed that the testing results demonstrate moderate reliability.
- To demonstrate validity of the performance measure score, developers used Poisson regression models to measure the association between STrR and other facility level outcomes, Standardized Mortality Ratio (SMR, NQF #0369) and Standardized Hospitalization Ratio (SHR, NQF 1463). The results from the Poisson model indicated that the StrR tertiles were significantly associated with both SMR and SHR. The developer also noted that a similar analysis was performed to compare StTR scores with facility-achieved hemoglobin levels; the analysis found that the percentage of patients with hemoglobin greater than 10 was positively associated with risk of transfusion.
- In addition, face validity was demonstrated, including a statement from the developers that six out of the six voting members of CMS's 2012 Technical Expert Panel voted to recommend the development of a facility-level standardized transfusion average. Overall, the Committee agreed that the testing results demonstrate moderate validity.

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3. Feasibility: H-15; M-4; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

<u>Rationale</u>:

- The Committee agreed that it is feasible to collect the data. Members also agreed that the data elements are generated as part of the care delivery process.

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4. Usability and Use: H-5; M-13; L-1; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is publically reported nationally in Dialysis Facility Compare (DFC) and will be in End Stage Renal Disease Quality Incentive Program (ESRD QIP) starting 2018.
- Committee members noted that a potential unintended consequence of the STrR would be to create an incentive for dialysis facilities to target higher hemoglobin levels, as targeting hemoglobin concentrations above 12 to 13 grams per deciliter is associated with elevated risk of cardiac events and related mortality. However, the Committee accepted the developer's rationale that the potential for unintended consequences is low with appropriate provider anemia management practices.

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5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-16; N-4**

6. Public and Member Comment

- The Kidney Care Partners notes that during the last project, this Standing Committee reviewed the STrR as #2699 and did not recommend it. The commenter expresses concern about the specifications, reliability, validity (risk model), and harmonization. In regards to validity, the commenter does not believe the new measure addressed the Committee's concerns about hospital- and physician-related factors. Overall, they remain concerned about the reliability, as well as the specifications and validity. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which document reliability issues with the STrR for small facilities, and comment specifically on the STrR's reliability for such facilities.
- The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person and maintained that the measure meets the NQF criteria.

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7. Consensus Standards Approval Committee (CSAC) Vote (November 2, 2016): Y-16; N-4

CSAC Decision: Approved for endorsement

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8. Board of Directors Vote (November 21, 2016): Yes

Board Decision: Ratified for endorsement

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9. Appeals

A stakeholder submitted an appeal of the endorsement decision on this measure, on the grounds that the Committee had not sufficiently discussed several key concerns about the measure. Upon review of the Committee's deliberations, it was determined that the Committee had considered and discussed the issues in question, and the appeal was not accepted.

Measures Not Endorsed

0260 Assessment of Health-Related Quality of Life in Dialysis Patients

Submission | Specifications

Description: Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year.

Numerator Statement: Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year

Denominator Statement: Number of individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis treated by the dialysis facility during the calendar year minus those dialysis patients who meet exclusion criteria in S.10.

Exclusions: Patients with ESRD (ICD-10 N18.6) on dialysis who are <18 years old; who are unable to complete the survey due to mental status that could invalidate the results; who are non-English speaking/reading and no native language translation or interpreter is available; or who have been on dialysis for <3 months. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed survey.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Process

Data Source: Patient Reported Data/Survey

Measure Steward: Witten and Associates, LLC

STANDING COMMITTEE MEETING [06/28/2016]

1. Importance to Measure and Report: Consensus as not reached on the Importance criteria

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

1a. Evidence: **H-0; M-5; L-3; I-12;** Evidence with Exception: **Y-14; N-6;** 1b. Performance Gap: **H-0; M-12; L-8; I-0**

Rationale:

- The developer provided updated evidence for this process measure, which was last reviewed in 2007. During the previous review, the evidence and testing was provided for the KDQOL survey, not the actual measure. For this review, the evidence presented is based on Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification; GUIDELINE 12. Based on 1989-2001 data, the evidence presented supports the recommendation that: “Patients with GFR <60 mL/min/1.73 m2 should undergo regular assessment for impairment of functioning and well-being: 1) to establish a baseline and monitor changes in functioning and well-being over time, and 2) to assess the effect of interventions on functioning and well-being.”
- Committee members raised concerns about the evidence being tangential to the measure as specified with little linkage to patient outcomes. Concerns were also raised about the validation of the KDQOL survey tool. Ultimately, the majority of the Committee voted to rate the

measure's evidence as insufficient with exception, noting it is reasonable to assume that in order for a provider to intervene on someone's functioning and well-being, a survey that assesses those items should be completed, and the very first step in that process is attempting to administer and deliver the survey.

- Using 2013-2015 KDQOL-Complete data, the developer tested whether there are statistically significant differences in the performance measure between facilities with at least 10 patients. Data from 2015 showed 1,261 facilities with a median score of 91.8 percent with an interquartile range of 78 to 100 percent. The tenth percentile was 61.2 percent. The Committee was not able to reach consensus on whether or not an opportunity for improvement in performance of this measure remains.

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2. Scientific Acceptability of Measure Properties: <u>The measure did not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: **H-3; M-8; L-9; I-0;** 2b. Validity: **H-0; M-2; L-16; I-2**

<u>Rationale</u>:

- The developer indicated that several exclusions changed since the last time the measure was reviewed in 2007. The exclusion of "<3 months at the facility" was revised to "<3 months on dialysis." The exclusion of patients with cognitive impairment, dementia, and psychosis was revised to "unable to complete due to mental status." The measure was also modified so that patients who refuse to complete the survey are not excluded. Lastly, the target population was broadened to include more than just seniors, since dialysis patients also include populations at risk, dual eligible beneficiaries, individuals with multiple chronic illnesses, and veterans.
- Committee members expressed concerns about the exclusions, specifically whether it is appropriate for patients who refuse to complete the survey to be included in the denominator. The developer's rationale for including these patients in the measure is that facilities need to track and make efforts to increase the number of patients completing the survey. There were also concerns that the mental status exclusion may be too broad and not well specified, allowing for inappropriate exclusions, and that more clarity for language exclusions may be needed as interpretation and attempts to implement may be highly variable between facilities.
- The developers provided empirical testing of computed performance scores for reportable clinics, which was conducted using a beta-binomial model. The internal reliability of the measure resulted in Cronbach's alpha of 0.926 for 2013, 0.925 for 2014, and 0.923 for 2015 from KDQOL-Complete data. In terms of understanding reliability in detecting signal to noise, a reliability score of 0.70 or greater is considered acceptable for drawing conclusions about groups. Some Committee members questioned if facility size indicated variation in reliability and if smaller facilities have lower reliability as compared to large dialysis facilities, although this was not included as part of the developer's analysis.
- The Committee was not able reach consensus on the reliability criterion.
- The developer presented validity testing results using linear mixed models with the patient-level quality of life scores for each scale as the dependent variable and facility completion rate as the main independent variable. Results demonstrated that higher completion rates were associated with statistically significantly higher patient-level quality of life scores within the facility.
- The developer also provided results of an exclusions analysis that assessed the odds of survey completion vs. refusal or exclusion across different subgroups, including age, gender, and race. Committee members questioned whether this was the most appropriate method for

demonstrating validity of this measure, and noted that the analyses suggested that case mix adjustment may be needed because of the differences in the odds of completion across different populations.

- The Committee did not pass the measure on the validity criterion and provided feedback to the developer.
- A reconsideration request was received. The developer provided clarification of the exclusion criteria and additional data supporting a performance gap; however, the Committee did not feel the additional information substantiated a re-vote on the non-passing criteria. It was noted that assessment of quality of life and specifically if dialysis is making an impact on ESRD patients is important, yet the current process measure was not the best mechanism to move in that direction.

Appendix B: NQF Renal Portfolio and Related Measures

Hemodialysis Measures

Measure Number	Title	Description	Measure Steward	Topic Area
0249	Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy--Minimum Delivered Hemodialysis Dose	Percentage of all adult (>=18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period.	Centers for Medicare & Medicaid Services	Hemodialysis
0323	Adult Kidney Disease: Hemodialysis Adequacy: Solute	Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for >= 90 days have a spKt/V >= 1.2	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)	Hemodialysis
0251	Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation 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 autogenous 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 separately); 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 versus prevalent patients, as defined by USRDS.	Kidney Care Quality Alliance	Hemodialysis Vascular Access
0256	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access	Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.	Centers for Medicare & Medicaid Services	Hemodialysis Vascular Access
0257	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles	Centers for Medicare & Medicaid Services	Hemodialysis Vascular Access
1421	Method of Adequacy Measurement for Pediatric Hemodialysis Patients	Percentage of pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.	Centers for Medicare & Medicaid Services	Pediatric Hemodialysis
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	Percentage of all pediatric (<18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V greater than or equal to 1.2	Centers for Medicare & Medicaid Services	Pediatric Hemodialysis

Peritoneal Dialysis Measures

Measure Number	Title	Description	Measure Steward	Topic Area
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	Percentage of all adult (>= 18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.	Centers for Medicare & Medicaid Services	Peritoneal Dialysis
0321	Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute	Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V >= 1.7 per week measured once every 4 months	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)	Peritoneal Dialysis

Dialysis Monitoring Measures

Measure Number	Title	Description	Measure Steward	Topic Area
0255	Measurement of Serum Phosphorus Concentration	Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.	Centers for Medicare & Medicaid Services	Dialysis Monitoring
0370	Monitoring hemoglobin levels below target minimum	Percentage of all adult (>=18 years old) hemodialysis patients, peritoneal dialysis, and home hemodialysis patients with ESRD >=3 months and who had Hb values reported for at least 2 of the 3 study months, who have a mean Hb <10.0 g/dL for a 3 month study period, irrespective of ESA use.	Centers for Medicare & Medicaid Services	Dialysis Monitoring
1425	Measurement of nPCR for Pediatric Hemodialysis Patients	Percentage of pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.	Centers for Medicare & Medicaid Services	Dialysis Monitoring
1454	Proportion of Patients with Hypercalcemia	Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	Centers for Medicare & Medicaid Services	Dialysis Monitoring
1666	Adult Kidney Disease : Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL	Percentage of calendar months within a 12-month period during which a hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy have a hemoglobin level > 12.0 g/dL	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)	Dialysis Monitoring
1418	Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients	Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis or home (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.	Centers for Medicare & Medicaid Services	Pediatric Dialysis Monitoring
1424	Monthly Hemoglobin Measurement for Pediatric Patients	Percentage of all pediatric (less than 18 years) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin.	Centers for Medicare & Medicaid Services	Pediatric Dialysis Monitoring
1667	Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)	Pediatric Dialysis Monitoring

Patient Safety Measures

Measure Number	Title	Description	Measure Steward	Topic Area
0260	Assessment of Health-related Quality of Life (Physical & Mental Functioning)	Percentage of dialysis patients who receive a quality of life assessment using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once per year.	RAND Corporation	
0369	Dialysis Facility Risk-adjusted Standardized Mortality Ratio	Risk-adjusted standardized mortality ratio for dialysis facility patients.	Centers for Medicare & Medicaid Services	Patient Safety
1460	Bloodstream Infection in Hemodialysis Outpatients	Adjusted ranking metric (ARM) and Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.	Centers for Disease Control and Prevention	Patient Safety
1463	Standardized Hospitalization Ratio for Admissions	Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.	Centers for Medicare & Medicaid Services	Patient Safety

Comorbid Conditions/Preventive Care Measures

Measure Number	Title	Description	Measure Steward	Topic Area
1668	Adult Kidney Disease: Laboratory Testing (Lipid Profile)	Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period	American Medical Association - Physician Consortium for Performance Improvement (AMA-PCPI)	Comorbid Conditions/Preventive Care

Additional Renal-Related Measures (Assigned to Other Projects)

Measure Number	Title	Description	Measure Steward	Standing Committee Assignment
0258	CAHPS In-Center Hemodialysis Survey	Percentage of patient responses to multiple testing tools. Tools include the In-Center Hemomdialysis Composite Score: The proportion of respondents answering each of response options for each of the items summed across the items within a composite to yield the composite measure score. (Nephrologists' Communication and Caring, Quality of Dialysis Center Care and Operations, Providing Information to Patients) Overall Rating: a summation of responses to the rating items grouped into 3 levels	Centers for Medicare & Medicaid Services	Person- and Family-Centered Care (Endorsement renewed 2015)
0062	Comprehensive Diabetes Care: Medical Attention for Nephropathy	The percentage of patients 18-75 years of age with diabetes (type 1 and type 2) who received a nephropathy screening test or had evidence of nephropathy during the measurement year.	National Committee for Quality Assurance	Endocrine (Endorsement renewed 2014)
0274	Diabetes Long-Term Complications Admission Rate (PQI 03)	Admissions for a principal diagnosis of diabetes with long-term complications (renal, eye, neurological, circulatory, or complications not otherwise specified) per 100,000 population, ages 18 years and older. Excludes obstetric admissions and transfers from other institutions.	Agency for Healthcare Research and Quality	Health and Well-Being (Endorsement renewed in 2014)
0226	Influenza Immunization in the ESRD Population (Facility Level)	Percentage of end stage renal disease (ESRD) patients aged 6 months and older receiving hemodialysis or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31 who either received, were offered and declined, or were determined to have a medical contraindication to the influenza vaccine.	Kidney Care Quality Alliance	Health and Well-Being (Endorsed in 2012; Under annual review)
0638	Uncontrolled Diabetes Admission Rate (PQI 14)	Admissions for a principal diagnosis of diabetes without mention of short-term (ketoacidosis, hyperosmolarity, or coma) or long-term (renal, eye, neurological, circulatory, or other unspecified) complications per 100,000 population, ages 18 years and older. Excludes obstetric admissions and transfers from other institutions.	Agency for Healthcare Research and Quality	Health and Well-Being (Endorsement Renewed in 2014)
0281	Urinary Tract Infection Admission Rate (PQI 12)	Admissions with a principal diagnosis of urinary tract infection per 100,000 population, ages 18 years and older. Excludes kidney or urinary tract disorder admissions, other indications of immunocompromised state admissions, obstetric admissions, and transfers from other institutions.	Agency for Healthcare Research and Quality	Health and Well-Being (Endorsement Renewed in 2014)
0114	Risk-Adjusted Postoperative Renal Failure	Percent of patients aged 18 years and older undergoing isolated CABG (without pre-existing renal failure) who develop postoperative renal failure or require dialysis	The Society of Thoracic Surgeons	Surgery (Endorsement Renewed in 2014)
0534	Hospital Specific Risk-Adjusted Measure of Mortality or One or More Major Complications Within 30 Days of a Lower Extremity Bypass (LEB)	Hospital specific risk-adjusted measure of mortality or one or more of the following major complications (cardiac arrest, myocardial infarction, CVA/stroke, on ventilator >48 hours, acute renal failure (requiring dialysis), bleeding/transfusions, graft/prosthesis/flap failure, septic shock, sepsis, and organ space surgical site infection), within 30 days of a lower extremity bypass (LEB) in patients age 16 and older.	American College of Surgeons	Surgery (Under review)
0327	Risk-Adjusted Average Length of Inpatient Hospital Stay	Percentage of inpatient & outpatients with excessive in-hospital days	Premier, Inc	All-Cause Admissions and Readmissions (Under Review)
2393	Pediatric All-Condition Readmission Measure	This measure calculates case-mix-adjusted readmission rates, defined as the percentage of admissions followed by 1 or more readmissions within 30 days, for patients less than 18 years old. The measure covers patients discharged from general acute care hospitals, including children's hospitals.	Center of Excellence for Pediatric Quality Measurement	All-Cause Admissions and Readmissions (Endorsed 2014)

Measure Number	Title	Description	Measure Steward	Standing Committee Assignment
0708	Proportion of Patients Hospitalized with Pneumonia that have a Potentially Avoidable Complication (during the Index Stay or in the 30-day Post-Discharge Period)	Percent of adult population aged 18 – 65 years who were admitted to a hospital with Pneumonia, were followed for one-month after discharge, and had one or more potentially avoidable complications (PACs). PACs may occur during the index stay or during the 30-day post discharge period (Please reference attached document labeled NQF Pneumonia PACs Risk Adjustment 2.16.10.xls, tabs labeled CIP_Index PAC_Stays and CIP_PAC_Readmission). We define PACs during each time period as one of three types: (A) PACs during the Index Stay (Hospitalization): (1) PACs related to the anchor condition: The index stay is regarded as having a PAC if during the index hospitalization the patient develops one or more of the avoidable complications that can result from pneumonia, such as respiratory failure, respiratory insufficiency, pneumothorax, pulmonary collapse, or requires respiratory intubation and mechanical ventilation, incision of pleura, thoracocentesis, chest drainage, tracheostomy etc. (2) PACs due to Comorbidities: The index stay is also regarded as having a PAC if one or more of the patient's controlled comorbid conditions is exacerbated during the hospitalization (i.e., it was not present on admission). Examples of these PACs are diabetic emergency with hypo- or hyperglycemia, stroke, coma, gastritis, ulcer, GI hemorrhage, acute renal failure etc. (3) PACs suggesting Patient Safety Failures: The index stay is regarded as having a PAC if there is one or more complication related to patient safety issues. Examples of these PACs are infections, sepsis, phlebitis, deep vein thrombosis, pulmonary embolism or any of the CMS-defined hospital acquired conditions (HACs). (B) PACs during the 30-day post discharge period: (1) PACs related to the anchor condition: Readmissions and emergency room visits during the 30-day post discharge period are considered PACs if they are for potentially avoidable complications of pneumonia such as respiratory failure, respiratory insufficiency, pneumonia, respiratory intubation, mechanical ventilation, etc. (2) PACs due to Comorbidities: Readmissions and emergency room visits during the 30-day post discharge period are also considered PACs if they are due to an exacerbation of one or more of the patient's comorbid conditions, such as a diabetic emergency with hypo- or hyperglycemia, stroke, coma, gastritis, ulcer, GI hemorrhage, acute renal failure etc. (3) PACs suggesting Patient Safety Failures: Readmissions or emergency room visits during the 30-day post discharge period are considered PACs if they are due to sepsis, infections, phlebitis, deep vein thrombosis, or for any of the CMS-defined hospital acquired conditions (HACs). The enclosed workbook labeled NQF Pneumonia PACs Risk Adjustment 2.16.10.xls, gives the frequency and costs associated with each of these types of PACs during the index hospitalization (tab labeled CIP_Index PAC_Stays) and for readmissions and emergency room visits during the 30-day post-discharge period (tab labeled CIP_PAC_Readmission). The information is based on a two-year national commercially insured population (CIP) claims database. The database had 4.7 million covered lives and $95 billion in "allowed amounts" for claims costs. The database was an administrative claims database with medical as well as pharmacy claims. The two tabs demonstrate the most common PACs that occurred in patients hospitalized with pneumonia.	Bridges To Excellence	Care Coordination (Endorsed in 2011; Undergoing Annual Review)

Measure Number	Title	Description	Measure Steward	Standing Committee Assignment
0705	Proportion of Patients Hospitalized with Stroke that have a Potentially Avoidable Complication (during the Index Stay or in the 30-day Post-Discharge Period)	Percent of adult population aged 18 – 65 years who were admitted to a hospital with stroke, were followed for one-month after discharge, and had one or more potentially avoidable complications (PACs). PACs may occur during the index stay or during the 30-day post discharge period (Please reference attached document labeled NQF_Stroke_PACs_Risk_Adjustment_2.16.10.xls, tabs labeled CIP_Index PAC_Stays and CIP_PAC_Readmission). We define PACs during each time period as one of three types: (A) PACs during the Index Stay (Hospitalization): (1) PACs related to the anchor condition: The index stay is regarded as having a PAC if during the index hospitalization for stroke the patient develops one or more complications such as hypertensive encephalopathy, malignant hypertension, coma, anoxic brain damage, or respiratory failure etc. that may result directly from stroke or its management. (2) PACs due to Comorbidities: The index stay is also regarded as having a PAC if one or more of the patient's controlled comorbid conditions is exacerbated during the hospitalization (i.e., it was not present on admission). Examples of these PACs are diabetic emergency with hypo- or hyperglycemia, pneumonia, lung complications, acute myocardial infarction, gastritis, ulcer, GI hemorrhage etc. (3) PACs suggesting Patient Safety Failures: The index stay is regarded as having a PAC if there are one or more complications related to patient safety issues. Examples of these PACs are septicemia, meningitis, other infections, phlebitis, deep vein thrombosis, pulmonary embolism or any of the CMS-defined hospital acquired conditions (HACs). (B) PACs during the 30-day post discharge period: (1) PACs related to the anchor condition: Readmissions and emergency room visits during the 30-day post discharge period after a stroke are considered as PACs if they are for hypertensive encephalopathy, malignant hypertension, respiratory failure, coma, anoxic brain damage etc. (2) PACs due to Comorbidities: Readmissions and emergency room visits during the 30-day post discharge period are also considered PACs if they are due to an exacerbation of one or more of the patient's comorbid conditions, such as a diabetic emergency with hypo- or hyperglycemia, pneumonia, lung complications, acute myocardial infarction, acute renal failure etc. (3) PACs suggesting Patient Safety Failures: Readmissions or emergency room visits during the 30-day post discharge period are considered PACs if they are due to sepsis, infections, deep vein thrombosis, pulmonary embolism, or for any of the CMS-defined hospital acquired conditions (HACs). The enclosed workbook labeled NQF_Stroke_PACs_Risk_Adjustment_2.16.10.xls, gives the frequency and costs associated with each of these types of PACs during the index hospitalization (tab labeled CIP_Index PAC_Stays) and for readmissions and emergency room visits during the 30-day post-discharge period (tab labeled CIP_PAC_Readmission). The information is based on a two-year national commercially insured population (CIP) claims database. The database had 4.7 million covered lives and $95 billion in "allowed amounts" for claims costs. The database was an administrative claims database with medical as well as pharmacy claims. The two tabs demonstrate the most common PACs that occurred in patients hospitalized with stroke.	Bridges to Excellence	Cardiovascular (Under Review)

Appendix C: Renal Portfolio—Use in Federal Programs

NQF #	Title	Federal Programs: Finalized as of June 12, 2015
0249	Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	Dialysis Facility Compare; End-Stage Renal Disease Quality Incentive Program
0256	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access	Dialysis Facility Compare; End-Stage Renal Disease Quality Incentive Program
0257	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	Dialysis Facility Compare; End-Stage Renal Disease Quality Incentive Program
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	Dialysis Facility Compare; End-Stage Renal Disease Quality Incentive Program
0321	Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute	Physician Feedback; Physician Quality Reporting System (PQRS); Value-Based Payment Modifier Program
0323	Adult Kidney Disease: Hemodialysis Adequacy: Solute	Physician Feedback; Physician Quality Reporting System (PQRS); Value-Based Payment Modifier Program
0369	Dialysis Facility Risk-adjusted Standardized Mortality Ratio	Dialysis Facility Compare
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	Dialysis Facility Compare; End-Stage Renal Disease Quality Incentive Program
1454	Proportion of patients with hypercalcemia	Dialysis Facility Compare; End-Stage Renal Disease Quality Incentive Program
1460	Bloodstream Infection in Hemodialysis Outpatients	End-Stage Renal Disease Quality Incentive Program
1463	Standardized Hospitalization Ratio for Admissions	Dialysis Facility Compare
1666	Adult Kidney Disease : Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL	Physician Feedback; Value-Based Payment Modifier Program
1667	Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	Physician Feedback; Physician Quality Reporting System (PQRS); Value-Based Payment Modifier Program
0258	CAHPS In-Center Hemodialysis Survey	End-Stage Renal Disease Quality Incentive Program
0114	Risk-Adjusted Postoperative Renal Failure	Physician Feedback; Physician Quality Reporting System (PQRS); Value-Based Payment Modifier Program
0281	Urinary Tract Infection Admission Rate (PQI 12)	Physician Feedback

Appendix D: Renal Standing Committee and NQF Staff

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Appendix E: Measure Specifications

0260 Assessment of Health-Related Quality of Life in Dialysis Patients

STEWARD

Witten and Associates, LLC

DESCRIPTION

Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year.

TYPE

Process

DATA SOURCE

Patient Reported Data/Survey Kidney Disease Quality of Life (KDQOL-36) survey

Available at measure-specific web page URL identified in S.1 No data dictionary

LEVEL

Facility

SETTING

Dialysis Facility

NUMERATOR STATEMENT

Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year

NUMERATOR DETAILS

Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis who complete a KDQOL-36 survey with or without assistance during the calendar year. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed a survey that year. A patient who completes more than one survey in a calendar year is counted only once.

DENOMINATOR STATEMENT

Number of individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis treated by the dialysis facility during the calendar year minus those dialysis patients who meet exclusion criteria in S.10.

DENOMINATOR DETAILS

Total number of individuals with ESRD (ICD-10 N18.6) on all types of dialysis at the dialysis facility minus patients who meet exclusion criteria in S.10.

EXCLUSIONS

Patients with ESRD (ICD-10 N18.6) on dialysis who are <18 years old; who are unable to complete the survey due to mental status that could invalidate the results; who are non-English speaking/reading and no native language translation or interpreter is available; or who have been on dialysis for <3 months. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed survey.

EXCLUSION DETAILS

1 - Age <18 calculated by date of exclusion minus date of birth in the medical record

2 - Unable to complete due to mental status (revised exclusion) from the medical record

3 - Non-English speaking/reading (no language translation or interpreter available) from medical record and RAND translations for KDQOL-36 and interpreter resources like www.LanguageLine.com or other service

4 - <3 months on dialysis (revised exclusion) calculated by date of exclusion minus date of first dialysis on Form CMS 2728 in medical record

RISK ADJUSTMENT

No risk adjustment or risk stratification

NA

STRATIFICATION

NA

TYPE SCORE

Categorical, e.g., yes/no passing score defines better quality

ALGORITHM

Number of completed surveys divided by the number of eligible dialysis patients (all treatment types) treated at the dialysis facility during the calendar year. Exclusion criteria are described in S.10. No diagram provided

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5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

0369 Standardized Mortality Ratio for Dialysis Facilities

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Standardized mortality ratio for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

TYPE

Outcome

DATA SOURCE

Administrative claims, Electronic Clinical 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.

No data collection instrument provided Attachment 0369_Data_Dictionary_Code_Table.xlsx

LEVEL

Facility

SETTING

Dialysis Facility

NUMERATOR STATEMENT

Number of deaths among eligible patients at the facility during the time period.

NUMERATOR DETAILS

Information on death is obtained from several sources which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the time period is calculated. This count includes only Medicare patients, as detailed below. It does not include deaths from street drugs or accidents unrelated to treatment: Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded from the calculations.

DENOMINATOR STATEMENT

Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.

DENOMINATOR DETAILS

UM-KECC's treatment history file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. SIMS/CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source. Information regarding first ESRD service date, death and transplant is obtained from additional sources including the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746) and the Social Security Death Master File.

The denominator for SMR for a facility is the total number of expected deaths identified using all patient-records at the facility meeting inclusion criteria. The number of days at risk in each of these patient-records is used to calculate the expected number of deaths for that patient-record.

The denominator is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities, calendar year, and body mass index (BMI) at incidence. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers. The results of this analysis are estimates of the regression coefficients in the Cox model and these provide an estimate of the relative risk for each patient. This is based on a linear predictor that arises from the Cox model, and is then used as an offset in the stage 2 model, which is unstratified and includes an adjustment for the race-specific age-adjusted state population death rates.

Assignment of Patients to Facilities

We detail patient inclusion criteria, facility assignment and how to count days at risk, all of which are required for the risk adjustment model. As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions below.

General Inclusion Criteria for Dialysis Patients

Since a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include a patient's follow-up into the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality and survival during the first 90 days of ESRD do not enter into the calculations. This minimum 90-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover renal function during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 60 days. This 60 day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. That is, deaths and survival during the first 60 days of dialysis at a facility do not affect the SMR of that facility.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility from day 61. In particular, a patient is attributed to their current facility on day 91 of ESRD if that facility had treated him or her for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients were removed from a facility's analysis upon receiving a transplant. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither paid dialysis claims nor SIMS information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

Days at Risk for Each Patient-Record

After patient treatment histories are defined as described above, periods of follow-up time (or patient-records) are created for each patient. A patient-record begins each time the patient is determined to be at a different facility or at the start of each calendar year. The number of days at risk starts over at zero for each patient record so that the number of days at risk for any patient-record is always a number between 0 and 365 (or 366 for leap years). Therefore, a patient who is in one facility for all four years gives rise to four patient-records and is analyzed the same way as would be four separate patients in that facility for one year each. When patients are treated at the same facility for two or more separate time periods during a year, the days at risk at the facility is the sum of all time spent at the facility for the year so that a given patient can generate only one patient-record per year at a given facility. For example, consider a patient who spends two periods of 100 days assigned to a facility, but is assigned to a different facility for the 165 days between these two 100-day periods. This patient will give rise to one patient-record of 200 days at risk at the first facility, and a separate patient-record of 165 days at risk at the second facility.

This measure is limited to Medicare dialysis patients. We require that patients reach a certain level of Medicare-paid dialysis bills to be included in the mortality statistics, or that patients have Medicare-paid inpatient claims during the period. Specifically, months within a given dialysis patient-period are used for SMR calculation when they meet the criterion of being within two months after a month with either: (a) $900+ of Medicare-paid dialysis claims OR (b) at least one Medicare-paid inpatient claim. The intention of this criterion is to assure completeness of information on hospitalizations for all patients included in the analysis.

Then we use the number of days at risk in each of these patient-records to calculate the expected number of deaths for that patient-record, and sum the total number of expected deaths during all patient-records at the facility as the expected number of death for that facility. Detailed methodology is described in Statistical Risk Model and Variables S.14.

EXCLUSIONS

N/A

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

Statistical risk model

The SMR is based on expected mortality calculated from a Cox model (Cox, 1972; SAS Institute Inc., 2004; Kalbfleisch and Prentice, 2002; Collett, 1994). The model used is fit in two stages. The stage 1 model is a Cox model stratified by facility and adjusted for patient age, race, ethnicity, sex, diabetes as cause of ESRD, duration of ESRD, nursing home status from previous year, patient comorbidities at incidence, prevalent comorbidities, calendar year and body mass index (BMI) at incidence. This model allows the baseline survival probabilities to vary between strata (facilities), and assumes that the regression coefficients are the same across all strata. Stratification by facility at this stage avoids biases in estimating regression coefficients that can occur if the covariate distributions vary substantially across centers.

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

•Age: We determine each patient's age for the birth date provided in the SIMS and REMIS databases. Age is included as a piecewise continuous variable with different coefficients based on whether the patient is 0-13 years old, 14-60 years old, or 61+ years old.

•Sex: We determine each patient's sex from his/her Medical Evidence Form (CMS-2728).

•Race (White, Black, Asian/PI, Native American or other): We determine race from REBUS/PMMIS, the EDB (Enrollment Data Base), and SIMS.

•Ethnicity (Hispanic, non-Hispanic or unknown): We determine ethnicity from his/her CMS-2728.

•Diabetes as cause of ESRD: We determine each patient's primary cause of ESRD from his/her CMS-2728.

•Duration of ESRD: We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types), the SIMS database and the SRTR database and categorize as less than one year, 1-2 years, 2-3 years, or 3+ years as of the period start date.

•Nursing home status in previous year: Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.

•BMI at incidence: We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term. The logarithm of BMI is included as a piecewise continuous log-linear term with different coefficients based on whether the log of BMI is greater or less than 3.5.

•Comorbidities at incidence: We determine each patient's comorbidities at incidence from his/her CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular

disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate indicator in the model, having a value of 1 if the patient has that comorbidity, and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where patients have at least one comorbidities. This variable has a value of 1 if the patient has at least one comorbidity and a value of 0 otherwise.

•Prevalent comorbidities: We identify a patient's prevalent comorbidities based on claims from the previous calendar year. The comorbidities adjusted for include those included in Appendix A.

•Calendar year: 2010-2013

•Missing indicator variables: Categorical indicator variables are included as covariates in the stage I model to account for records with missing values for cause of ESRD, comorbidity at incidence(missing CMS-2728 form), and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. BMI is imputed when either missing, or outside the range of [10,70) for adults or [5,70) for children. To impute BMI, we used the average values of the group of patients with similar characteristics (age, race, sex, diabetes) when data for all four of these characteristics were available. If either race or diabetes was also missing, the imputation was based on age and sex only. If either age or sex is missing, the patient is excluded from computations.

Beside main effects, two-way interaction terms between age, race, ethnicity, sex duration of ESRD and diabetes as cause of ESRD are also included:

•Age*Race: Black

•Ethnicity*Race: Non-White

•Diabetes as cause of ESRD*Race

•Diabetes as cause of ESRD*Vintage

•Duration of ESRD: less than or equal to 1 year *Race

•Duration of ESRD: less than or equal to 1 year* Sex

•Diabetes as cause of ESRD*Sex

•Sex*Race: Black

Available in attached Excel or csv file at S.2b

STRATIFICATION

N/A

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

See flowchart in Appendix. Available in attached appendix at A.1

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5.1 Identified measures: 1463 : Standardized Hospitalization Ratio for Dialysis Facilities

2496 : Standardized Readmission Ratio (SRR) for dialysis facilities

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: The specifications are not completely harmonized. Each measure assesses different outcomes as reflected in certain differences across the measure specifications. SMR, and SHR and SRR are harmonized to the population they measure (Medicare-covered ESRD patients), methods (SMR and SHR) and certain risk adjustment factors specific to the ESRD population. SMR and SHR adjust for the same comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach. The differences between SMR and SHR and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SMR and SHR adjust for a set of prevalent comorbidities (observed in a prior year), however the complete set of comorbidities for SMR differs from SRR. SRR, a measure of hospital utilization adjusts for planned readmissions; and for discharging hospital, acknowledging that for readmission, hospitals also bear accountability for properly coordinating care with the dialysis facility. These risk adjustments in SRR account for those characteristics specifically associated with readmission, and do not apply to SMR. Only SMR adjusts for state death rates, race, and ethnicity to account for these respective differences related to mortality outcomes and that are deemed outside of a facility's control.

5b.1 If competing, why superior or rationale for additive value: N/A

1463 Standardized Hospitalization Ratio for Dialysis Facilities

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Standardized hospitalization ratio for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

TYPE

Outcome

DATA SOURCE

Administrative claims, Electronic Clinical 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.

In calculating the SHR, Medicare inpatient claims that are adjacent or overlap with another claim are collapsed into one record. Specifically, if the admission date of an inpatient record is within one day of a following admission's discharge date, these adjacent inpatient records will be collapsed into one inpatient record that takes on the first admission's admission date and the following admission's discharge date. Similarly, if an inpatient record overlaps with another inpatient record, the two records are collapsed into one record where the earliest admission date between the two records becomes the new admission date and the latest discharge date between the two records becomes the new discharge date.

No data collection instrument provided Attachment 1463_Data_Dictionary_Code_Table.xlsx

LEVEL

Facility

SETTING

Dialysis Facility

NUMERATOR STATEMENT

Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.

NUMERATOR DETAILS

The numerator is calculated through use of Medicare claims data. When a claim is made for an inpatient hospitalization, the patient is identified and attributed to a dialysis facility following rules discussed below in the denominator details. The numerator is the count of all such hospitalizations over the reporting period.

DENOMINATOR STATEMENT

Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.

DENOMINATOR DETAILS

Assignment of Patients to Facilities

UM-KECC's treatment history file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. SIMS/CROWNWeb is the primary basis for placing patients at dialysis facilities, and dialysis claims are used as an additional source. Information regarding first ESRD service date, death and transplant is obtained from additional sources including the CMS Medical Evidence Form (Form CMS-2728), transplant data from the Organ Procurement and Transplant Network (OPTN), the Death Notification Form (Form CMS-2746) and the Social Security Death Master File.

As patients can receive dialysis treatment at more than one facility in a given year, we assign each patient day to a facility (or no facility, in some cases) based on a set of conventions described below, which largely align with those for the Standardized Mortality Ratio (SMR). We detail patient inclusion criteria, facility assignment and how to count days at risk, all of which are required for the risk adjustment model.

General Inclusion Criteria for Dialysis Patients

Though a patient's follow-up in the database can be incomplete during the first 90 days of ESRD therapy, we only include a patient's follow-up in the tabulations after that patient has received chronic renal replacement therapy for at least 90 days. Thus, hospitalizations, mortality and survival during the first 90 days of ESRD do not enter into the calculations. This minimum 90-day period also assures that most patients are eligible for Medicare, either as their primary or secondary insurer. It also excludes from analysis patients who die or recover renal function during the first 90 days of ESRD.

In order to exclude patients who only received temporary dialysis therapy, we assign patients to a facility only after they have been on dialysis there for the past 60 days. This 60 day period is used both for patients who started ESRD for the first time and for those who returned to dialysis after a transplant. That is, hospitalizations during the first 60 days of dialysis at a facility do not affect the SHR of that facility.

Identifying Facility Treatment Histories for Each Patient

For each patient, we identify the dialysis provider at each point in time. Starting with day 91 after onset of ESRD, we attribute patients to facilities according to the following rules. A patient is attributed to a facility once the patient has been treated there for the past 60 days. When a patient transfers from one facility to another, the patient continues to be attributed to the original facility for 60 days and then is attributed to the destination facility. In particular, a patient is attributed to his or her current facility on day 91 of ESRD if that facility had treated him or her for the past 60 days. If on day 91, the facility had not treated a patient for the past 60 days, we wait until the patient reaches day 60 of continuous treatment at that facility before attributing the patient to that facility. When a patient is not treated in a single facility for a span of 60 days (for instance, if there were two switches within 60 days of each other), we do not attribute that patient to any facility. Patients are removed from facilities three days prior to transplant in order to exclude the transplant hospitalization. Patients who withdrew from dialysis or recovered renal function remain assigned to their treatment facility for 60 days after withdrawal or recovery.

If a period of one year passes with neither paid dialysis claims nor SIMS information to indicate that a patient was receiving dialysis treatment, we consider the patient lost to follow-up and do not include that patient in the analysis. If dialysis claims or other evidence of dialysis reappears, the patient is entered into analysis after 60 days of continuous therapy at a single facility.

Days at Risk for Medicare Dialysis Patients

After patient treatment histories are defined as described above, periods of follow-up in time since ESRD onset are created for each patient. In order to adjust for duration of ESRD appropriately, we define 6 time intervals with cut points at 6 months, 1 year, 2 years, 3 years and 5 years. A new time period begins each time the patient is determined to be at a different facility, or at the start of each calendar year or when crossing any of the above cut points.

Since hospitalization data tend not to be as complete as mortality data, we include only patients whose Medicare billing records include all hospitalizations. To achieve this goal, we require that patients reach a certain level of Medicare-paid dialysis bills to be included in the hospitalization

statistics, or that patients have Medicare-paid inpatient claims during the period. Specifically, months within a given dialysis patient-period are used for SHR calculation when they meet the criterion of being within two months after a month with either: (a) $900+ of Medicare-paid dialysis claims OR (b) at least one Medicare-paid inpatient claim. The intention of this criterion is to assure completeness of information on hospitalizations for all patients included in the analysis.

The number of days at risk in each of these patient-ESRD facility-year time periods is used to calculate the expected number of hospital admissions for the patient during that period. The SHR for a facility is the ratio of the total number of observed hospitalizations to the total number of expected hospitalizations during all time periods at the facility. Based on a risk adjustment model for the overall national hospitalization rates, we compute the expected number of hospitalizations that would occur for each month that each patient is attributed to a given facility. The sum of all such expectations for patients and months yields the overall number of hospital admissions that would be expected given the specific patient mix and this forms the denominator of the measure.

The denominator of the SHR stems from a proportional rates model (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). This is the recurrent event analog of the well-known proportional hazards or Cox model (Cox, 1972; Kalbfleisch and Prentice, 2002). To accommodate large-scale data, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and the computational methodology developed in Liu, Schaubel and Kalbfleisch (2012).

References:

Cook, R. and Lawless, J. The Statistical Analysis of Recurrent Events. New York: Springer. 2007.

Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society, Series B, 34, 187-220.

Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.

Lawless, J. F. and Nadeau, C. Some simple and robust methods for the analysis of recurrent events, Technometrics, 37 1995, 355-364.

Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. Semi parametric regression for the mean and rate functions of recurrent events, Journal of the Royal Statistical Society Series B, 62, 2000, 771-730

Liu, D., Schaubel, D.E. and Kalbfleisch, J.D. Computationally efficient marginal models for clustered recurrent event data, University of Michigan Department of Biostatistics Technical Reports, 2010.

EXCLUSIONS

None.

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

Statistical risk model

The regression model used to compute a facility's "expected" number of hospitalizations for the SHR measure contains many factors thought to be associated with hospitalization rates.

Specifically, the model adjusts for patient age, sex, diabetes as cause of ESRD, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, prevalent comorbidities, and calendar year. The stage 1 model allows the baseline hospitalization rates to vary between strata, which are defined by facilities, but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. In essence, it avoids a possible confounding between facility effects and patient covariates as can arise, for example, if patients with favorable values of the covariate tend to be treated at facilities with better treatment policies and outcomes. Thus, for example, if patients with diabetes as a cause of ESRD tended to be treated at better facilities, one would underestimate the effect of diabetes unless the model is adjusted for facility. In this model, facility adjustment is done by stratification.

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

•Age: We determine each patient's age for the birth date provided in the SIMS and REMIS databases and group patients into the following categories: 0-14 years old, 15-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old.

•Sex: We determine each patient's sex from his/her Medical Evidence Form (CMS-2728).

•Diabetes as cause of ESRD: We determine each patient's primary cause of ESRD from his/her CMS-2728.

•Duration of ESRD: We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types), the SIMS database and the SRTR database and categorize as 91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date.

•Nursing home status: Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.

•BMI at incidence: We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.

•Comorbidities at incidence are determined using a selection of comorbidities reported on the CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the model.

•Prevalent comorbidities: We identify a patient's prevalent comorbidities based on claims from the previous calendar year. The comorbidities adjusted for include those listed in data dictionary/code table (excel file).

•Calendar year

Categorical indicator variables are included as covariates in the stage I model to account for records with missing values for cause of ESRD, comorbidities at incidence (missing CMS-2728), and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where the patient has at least one of the incident comorbidities listed earlier. This variable has a value of 1 if the patient has at least one of the comorbidities and a value of 0 otherwise.

Beside main effects, two-way interaction terms between age, sex and duration and cause of ESRD are also included:

•Diabetes as cause of ESRD*Duration of ESRD

•Diabetes as cause of ESRD*Sex

•Diabetes as cause of ESRD*Age

•Age*Sex

Available in attached Excel or csv file at S.2b

STRATIFICATION

N/A

TYPE SCORE

Ratio better quality = lower score

ALGORITHM

See flowchart in appendix. Available in attached appendix at A.1

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5.1 Identified measures: 0369 : Standardized Mortality Ratio for Dialysis Facilities

2496 : Standardized Readmission Ratio (SRR) for dialysis facilities

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: These measures are not completely harmonized. Each measure assesses different outcomes as reflected in certain differences across the measure specifications. SHR, SMR and SRR are harmonized to the population they measure (Medicare-covered ESRD patients), methods (SMR and SHR) and certain risk adjustment factors specific to the ESRD population. SHR and SMR adjust for all the same comorbidity risk factors, a similar set of patient characteristics, and use fixed effects in their modeling approach. The differences between SHR, SMR and SRR reflect adjustment for factors specific to the outcome of each respective measure. Both SHR and SMR adjust for a set of prevalent comorbidities (observed in a prior year), however the complete set of comorbidities differs for SRR. SRR excludes planned readmissions; and adjusts for discharging hospital, acknowledging that for readmission, hospitals also bear accountability for properly coordinating care with the dialysis facility. These risk adjustments in SRR account for those characteristics specifically associated with readmission, and do not apply to SHR or SMR. SHR adjusts for sex to account for sex-age specific effects associated with higher hospitalization. Only SMR adjusts for state death rates, race, and ethnicity to account for these respective differences related to mortality outcomes and that are deemed outside of a facility's control.

5b.1 If competing, why superior or rationale for additive value: N/A

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

TYPE

Intermediate Clinical Outcome

DATA SOURCE

Administrative claims, Electronic Clinical Data CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims and the CMS Medical Evidence form 2728 are data sources for the risk adjustment factors. Medicare claims and CROWNWeb are used for the exclusion criteria.

No data collection instrument provided Attachment 2977_Data_Dictionary_Code_Table.xlsx

LEVEL

Facility

SETTING

Dialysis Facility

NUMERATOR STATEMENT

The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.

NUMERATOR DETAILS

The number of patient-months using an AVF as the sole means of vascular access at a given facility, adjusted for patient-mix.

An AVF is considered in use if the CROWNWeb “Access Type IDs” of 14 or 22 has been recorded for a given month, where “14” represents AV fistula only (with 2 needles) and “22” represents AV fistula only with an approved single needle device.

DENOMINATOR STATEMENT

All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the entire reporting month at the same facility.

DENOMINATOR DETAILS

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are on in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

EXCLUSIONS

Exclusions that are implicit in the denominator definition include:

•Pediatric patients (<18 years old)

•Patients on Peritoneal Dialysis

•Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

•Patients under hospice care in the current reporting month

•Patients with metastatic cancer in the past 12 months

•Patients with end stage liver disease in the past 12 months

•Patients with coma or anoxic brain injury in the past 12 months

EXCLUSION DETAILS

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file).

RISK ADJUSTMENT

Statistical risk model

The proposed SFR measure is a directly standardized percentage, in that each facility's percentage of AVF use is adjusted to the national distribution of covariates (risk factors) (with 'national' here referring to all-facilities-combined). The SFR for facility i is an estimate of what the facility's percentage of AVF would equal if the facility's patient mix was equal to that of the nation as a whole. The measure is adjusted for patient demographic and clinical characteristics based on a logistic regression model. This model includes the facility indicators and assumes that the regression coefficients of risk factors are the same across all facilities. The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects.

The patient characteristics included in the logistic regression model as covariates are:

- Age
- BMI at incidence
- Nursing home status in previous year
- Nephrologist's care prior to ESRD
- Duration of ESRD
- Inability to ambulate/transfer at ESRD incidence (CMS-2728 form)
- Comorbidities either at ESRD incidence (CMS-2728 form) or prevalent comorbidities based on Medicare claims filed in prior 12 months
  - Diabetes
  - Heart diseases
  - Peripheral vascular disease
  - Cerebrovascular disease
  - Chronic obstructive pulmonary disease
  - Anemia (unrelated to ESRD/CKD)
  - Non-Vascular Access-Related Infections
  - Drug dependence
- Indicator for Medicare coverage for at least 6 months during the past 12 months

Available in attached Excel or csv file at S.2b

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

See calculation flowchart in Appendix. Available in attached appendix at A.1

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5.1 Identified measures: 0251 : Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

2594 : Optimal End Stage Renal Disease (ESRD) Starts

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components in addition to assessing fistula use. It is a referral process measure. The most basic requirement to get into the numerator is referral to a vascular surgeon (or other qualified physician). This has the potential for facilities to score well on the measure separate from whether patients are receiving treatment with a fistula, graft, or catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of this fistula measure to function as a more direct incentive to encourage fistula use. Moreover, consistent with the concerns and recommendations made by the vascular access TEP, the SFR is risk adjusted and includes risk factors to account for patients where fistula may not be the appropriate access type. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the SFR includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

2978 Hemodialysis Vascular Access: Long-Term Catheter Rate

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

TYPE

Intermediate Clinical Outcome

DATA SOURCE

Administrative claims, Electronic Clinical Data CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims are used for the comorbidity conditions exclusion criteria.

No data collection instrument provided Attachment 2978_Data_Dictionary_Code_Table.xlsx

LEVEL

Facility

SETTING

Dialysis Facility

NUMERATOR STATEMENT

The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

NUMERATOR DETAILS

The number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last day of the reporting month.

For a given month, if any of the following CROWNWeb "Access Type IDs" (16,18,19,20,21,"·") has been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

DENOMINATOR STATEMENT

All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

DENOMINATOR DETAILS

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

EXCLUSIONS

Exclusions that are implicit in the denominator definition include:

-Pediatric patients (<18 years old)

-Patients on Peritoneal Dialysis

-Patient-months under in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

-Patients under hospice care in the current reporting month

-Patients with metastatic cancer in the past 12 months

-Patients with end stage liver disease in the past 12 months

-Patients with coma or anoxic brain injury in the past 12 months

EXCLUSION DETAILS

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are < 18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claim types. Medicare claims include inpatient hospitalizations, outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file)

RISK ADJUSTMENT

No risk adjustment or risk stratification

N/A

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = lower score

ALGORITHM

See calculation flowchart in Appendix. Available in attached appendix at A.1

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5.1 Identified measures: 0251 : Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

2594 : Optimal End Stage Renal Disease (ESRD) Starts

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components including AV fistula use, AV graft use or referral to a vascular surgeon (or other qualified physician) if using a long-term catheter. It is a referral process measure for those patients with a catheter. This has the potential for facilities to score well on the measure even if they have patients with a catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of the catheter measure to function as a more direct disincentive to prolonged catheter use, consistent with the concerns and recommendations made by the vascular access TEP. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on prolonged catheter use. These suggest fundamental differences in measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the long-term catheter rate measure includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

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

Administrative claims, Electronic Clinical 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).

No data collection instrument provided Attachment 2979_Code_Table_and_Risk_Model.xlsx

LEVEL

Facility

SETTING

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 the presence in a Medicare inpatient claim of the appropriate ICD-9 procedure codes (99.03, 99.04), or, value code (37). For inpatient transfusion events that are identified using specific ICD-9 procedure codes (99.03, 99.04), we identify a transfusion event for each transfusion procedure code with a corresponding unique date listed on the inpatient claim, thus allowing determination of multiple transfusion events on inpatient claims with multiple ICD-9 procedure codes present. For inpatient claims with value code (37), we count a single transfusion event regardless of the number of transfusion value codes reported, so that the number of discrete events counted is the same whether the claim value code indicates 1 unit of blood or multiple units of blood. This results in a more conservative estimate of blood transfusion events from inpatient claims with transfusion value codes.

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); or, value code (37). In outpatient claims we count a transfusion event for each HCPCS and corresponding unique revenue center date to determine the number of unique transfusion events. Therefore multiple corresponding unique dates for revenue center codes will result in multiple transfusions events, while multiple HCPCS codes reported for the same revenue center date are counted as a single transfusion event, regardless of the number of units of blood recorded. For example, a HCPCS indicating 3 pints of blood reported for two different revenue center dates would equal two transfusion events, while a HCPCS indicating 3 pints of blood reported with the same revenue center date would be counted as a single transfusion event. Finally, outpatient claims with a transfusion related value code (37) is counted as one event.

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 1 year free of claims that contain these exclusion eligible diagnoses.

EXCLUSION DETAILS

We performed multivariate logistic regression demonstrating that a 1-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 Appendix, a hypothetical patient has patient-

years at risk at a facility from 1/1/2008 to 12/31/2011. Review of Medicare claims identified presence of one or more exclusion comorbidities 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 towards the facility's total transfusion event count because the presence of the exclusion comorbidity claims within the 1-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 1-year gap between this transfusion event and the last claim observed with the exclusion diagnosis.

RISK ADJUSTMENT

Statistical risk model

The denominator of the "STrR" uses expected transfusions calculated from a Cox model (Cox, 1972) as extended to handle repeated events (Lawless and Nadeau, 1995; Lin et al., 2000; Kalbfleisch and Prentice, 2002). For computational purposes, we adopt a model with piecewise constant baseline rates (e.g. Cook and Lawless, 2007) and computational methodology as developed in Liu, Schaubel and Kalbfleisch (2010). A stage 1 model is first fitted to the national data with piecewise-constant baseline rates stratified by facility; transfusion rates are adjusted for patient age, diabetes, duration of ESRD, nursing home status, BMI at incidence, comorbidities at incidence, and calendar year. This model allows the baseline transfusion rates to vary between strata (facilities), but assumes that the regression coefficients are the same across all strata; this approach is robust to possible differences between facilities in the patient mix being treated. The linear predictor for each patient based on the regression coefficients in the stage 1 model is used to compute a risk adjustment factor that is then used as an offset in the stage 2 model to estimate the population baseline rate without stratifying facilities.

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

•Age: We determine each patient's age for the birth date provided in the SIMS and REMIS databases and group patients into the following categories: 0-14 years old, 15-24 years old, 25-44 years old, 45-59 years old, 60-74 years old, or 75+ years old.

•Diabetes as cause of ESRD: We determine each patient's primary cause of ESRD from his/her CMS-2728.

•Duration of ESRD: We determine each patient's length of time on dialysis using the first service date from his/her CMS-2728, claims history (all claim types), the SIMS database and the SRTR database and categorize as 91 days-6 months, 6 months-1 year, 1-2 years, 2-3 years, 3-5 years, or 5+ years as of the period start date.

•Nursing home status: Using the Nursing Home Minimum Dataset, we determine if a patient was in a nursing home the previous year.

•BMI at incidence: We calculate each patient's BMI as the height and weight provided on his/her CMS 2728. BMI is included as a log-linear term.

•Comorbidities at ESRD incidence are determined using a selection of comorbidities reported on the CMS-2728 namely, alcohol dependence, atherosclerotic heart disease, cerebrovascular disease, chronic obstructive pulmonary disease, congestive heart failure, diabetes (includes currently on insulin, on oral medications, without medications, and diabetic retinopathy), drug dependence, inability to ambulate, inability to transfer, malignant neoplasm, cancer, other

cardiac disease, peripheral vascular disease, and tobacco use (current smoker). Each comorbidity is included as a separate covariate in the model.

•Calendar year

•Categorical indicator variables are included as covariates in the stage I model to account for records with missing values for cause of ESRD, comorbidities at incidence (missing CMS-2728), and BMI. These variables have a value of 1 if the patient is missing the corresponding variable and a value of 0 otherwise. Another categorical indicator variable is included as a covariate in the stage 1 model to flag records where the patient has at least one of the incident comorbidities listed earlier. This variable has a value of 1 if the patient has at least one of the comorbidities and a value of 0 otherwise.

Beside main effects, two-way interaction terms between age and duration and cause of ESRD are also included:

•Diabetes as cause of ESRD*Duration of ESRD

•Diabetes as cause of ESRD*Age

The same coefficient weights are used as in the Standardized Hospitalization Ratio (see www.dialysisdata.org; NQF #1463 http://www.qualityforum.org/QPS/1463).

Coefficients can be found in the attached excel file.

References: Cox, D.R. (1972) Regression Models and Life Tables (with Discussion). J. Royal statistical Society, Series B, 34, 187-220.

Cook, R. and Lawless, J. The Statistical Analysis of Recurrent Events. New York: Springer. 2007.

Cook, R. and Lawless, J. Marginal analysis of recurrent events and a terminal event. Statistics in Medicine 1997; 16: 911-924.

Kalbfleisch, J.D. and Prentice, R. L. The Statistical Analysis of Failure Time Data. Wiley, New York, 2002.

Lawless, J. F. and Nadeau, C. Some simple and robust methods for the analysis of recurrent events, Technometrics, 37 1995, 355-364.

Lin, D.Y., Wei, L.J., Yang, I. and Ying, Z. Semi parametric regression for the mean and rate functions of recurrent events, Journal of the Royal Statistical Society Series B, 62, 2000, 771-730

Liu, D., Schaubel, D.E. and Kalbfleisch, J.D. Computationally efficient marginal models for clustered recurrent event data, University of Michigan Department of Biostatistics Technical Reports, 2010.

Available in attached Excel or csv file at S.2b

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). Available in attached appendix at A.1

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

Appendix F1: Related and Competing Measures (Tabular Format)

Comparison of NQF 0251, NQF 0256, NQF 2977, and NQF 2978

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
Steward	Kidney Care Qualuty Alliance (KCQA)	Centers for Medicare & Medicaid Services	Centers for Medicare & Medicaid Services	Centers for Medicare & Medicaid Services
Description	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 autogenous AVF (defined as two needles used or a single-needle device]) (computed and reported separately); 2. have a functional AV graft (computed and reported separately); 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).	Percentage of patient months on maintenance hemodialysis during the last HD treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.	Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.	Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.			
Type	Process	Outcome	Intermediate Clinical Outcome	Intermediate Clinical Outcome
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records Data elements for the measure can be collected via the CROWNWeb Electronic Data Interchange, available at URL: http://www.projectcrownweb.org/crown/index.php. No data collection instrument provided Attachment KCQA0251_DataDictionary02-26-15.pdf	Administrative claims, Electronic Clinical Data CROWNWeb is the primary data source. However, this measure can be collected through Medicare claims data (since July 2010) and Fistula First Breakthrough Initiative data (though the definition of the measure is slightly different). The measure has been publically reported using claims data since 2013. No data collection instrument provided No data dictionary	Administrative claims, Electronic Clinical Data CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims and the CMS Medical Evidence form 2728 are data sources for the risk adjustment factors. Medicare claims and CROWNWeb are used for the exclusion criteria. No data collection instrument provided Attachment 2977_Data_Dictionary_Code_Table.xlsx	Administrative claims, Electronic Clinical Data CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims are used for the comorbidity conditions exclusion criteria. No data collection instrument provided Attachment 2978_Data_Dictionary_Code_Table.xlsx
Level	Clinician : Individual	Facility	Facility	Facility
Setting	Ambulatory Care : Clinician Office/Clinic, Dialysis Facility	Dialysis Facility	Dialysis Facility	Dialysis Facility
Numerator Statement	Number of patients from the denominator who: 1. have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or	Number of patient months in the denominator who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the month.	The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.	The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	2. have a functional AV graft (computed and reported separately); 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 (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately). Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.			
Numerator Details	Include in the numerator all patients from the denominator who meet the following criteria: 1. Access type = Functional autogenous AVF (defined as 2 needles used or single-needle device) (NOTE: 1 needle used in a 2-needle device is NOT acceptable) OR 2. Access type = • Functional AV graft OR • AVF combined with AV graft OR • Catheter (alone or combined with an AVF or AV graft)	Number of patient months in the denominator who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the month.	The number of patient-months using an AVF as the sole means of vascular access at a given facility, adjusted for patient-mix. An AVF is considered in use if the CROWNWeb "Access Type IDs" of 14 or 22 has been recorded for a given month, where "14" represents AV fistula only (with 2 needles) and "22" represents AV fistula only with an approved single needle device.	The number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last day of the reporting month. For a given month, if any of the following CROWNWeb "Access Type IDs" (16,18,19,20,21,"·") has been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	AND a. Patient 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 an AVF or AV graft during the 12-month reporting period AND b. Facility medical records contain the following types of documentation of the surgical evaluation: • A note or letter prepared by the primary nephrologist OR • A note or letter prepared by the vascular surgeon, other qualified surgeon, or interventional nephrologist trained in the primary placement of vascular access OR • A note prepared by facility personnel AND • Date of the surgical evaluation: (MM/YYYY) AND • If permanent access was not placed, the reason for this decision.			reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "." represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
Denominator Statement	All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days. This measure includes both in-center and home hemodialysis patients.	The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the entire reporting month at the same facility.	All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.
Denominator Details	Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice: 1. Diagnosis = ESRD AND 2. Primary type of dialysis = hemodialysis or home hemodialysis AND 3. Age = >/= 18 years AND 4. Time on dialysis = >90 days	Adult hemodialysis patients who have had ESRD for greater than 90 days as of of the first day of the reporting month.	For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are on in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month. To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month. The monthly patient count at a facility includes all eligible prevalent and incident patients.	For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month. To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month. The monthly patient count at a facility includes all eligible prevalent and incident patients.

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
			The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.	The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.
Exclusions	None.	The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. For both CROWNWeb and Claims data, the denominator will include all hemodialysis patients who are at least 18 years old and have had ESRD for greater than 90 days as	Exclusions that are implicit in the denominator definition include: •Pediatric patients (<18 years old) •Patients on Peritoneal Dialysis •Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility In addition, the following exclusions are applied to the denominator: Patients with a catheter that have limited life expectancy: •Patients under hospice care in the current reporting month •Patients with metastatic cancer in the past 12 months •Patients with end stage liver disease in the past 12 months •Patients with coma or anoxic brain injury in the past 12 months	Exclusions that are implicit in the denominator definition include: -Pediatric patients (<18 years old) -Patients on Peritoneal Dialysis -Patient-months under in-center or home hemodialysis for less than a complete reporting month at the same facility In addition, the following exclusions are applied to the denominator: Patients with a catheter that have limited life expectancy: -Patients under hospice care in the current reporting month -Patients with metastatic cancer in the past 12 months -Patients with end stage liver disease in the past 12 months -Patients with coma or anoxic brain injury in the past 12 months

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
		of the first day of the reporting month.		
Exclusion Details	Not applicable.	Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old), and acute hemodialysis patients (hemodialysis patients who have had ESRD for less than 91 days). There are no additional exclusions for this measure.	Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month. The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded. For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21"	Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month. The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are < 18 years old as of the first day of the reporting month are excluded. For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21"

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
			represents other/unknown, and "·" represents missing. Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month. Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file).	represents other/unknown, and "·" represents missing. Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month. Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claim types. Medicare claims include inpatient hospitalizations, outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file).

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
Risk Adjustment	No risk adjustment or risk stratification Not applicable.	See above denominator details.	Statistical risk model The proposed SFR measure is a directly standardized percentage, in that each facility's percentage of AVF use is adjusted to the national distribution of covariates (risk factors) (with 'national' here referring to all-facilities-combined). The SFR for facility i is an estimate of what the facility's percentage of AVF would equal if the facility's patient mix was equal to that of the nation as a whole. The measure is adjusted for patient demographic and clinical characteristics based on a logistic regression model. This model includes the facility indicators and assumes that the regression coefficients of risk factors are the same across all facilities. The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects. The patient characteristics included in the logistic regression model as covariates are: •Age •BMI at incidence •Nursing home status in previous year •Nephrologist's care prior to ESRD •Duration of ESRD	No risk adjustment or risk stratification N/A

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
			•Inability to ambulate/transfer at ESRD incidence (CMS-2728 form) •Comorbidities either at ESRD incidence (CMS-2728 form) or prevalent comorbidities based on Medicare claims filed in prior 12 months oDiabetes oHeart diseases oPeripheral vascular disease oCerebrovascular disease oChronic obstructive pulmonary disease oAnemia (unrelated to ESRD/CKD) oNon-Vascular Access-Related Infections oDrug dependence •Indicator for Medicare coverage for at least 6 months during the past 12 months Available in attached Excel or csv file at S.2b	
Stratification	Not applicable.	No risk adjustment or risk stratification N/A	N/A	N/A
Type Score	Rate/proportion better quality = higher score	N/A	Rate/proportion better quality = higher score	Rate/proportion better quality = lower score
Algorithm	The measure score is calculated by dividing the total number of patients included in the numerator by the total number of patients included in the denominator.	Rate/proportion better quality = lower score For this measure calculation, the numerator will be divided by the denominator.Calculation of the	See calculation flowchart in Appendix. Available in attached appendix at A.1	See calculation flowchart in Appendix. Available in attached appendix at A.1

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	IDENTIFICATION OF DENOMINATOR CASES To identify patients in the denominator, first calculate the following: • Patient age = (Date of first day of most recent month of study period)—(Patient's Date of Birth) • Patient time on dialysis = (Date of first day of most recent month of study period)—(Patient's Date Regular Chronic Dialysis Began) Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice: 1. Diagnosis = ESRD AND 2. Primary type of dialysis = hemodialysis or home hemodialysis AND 3. Age = >/=18 years AND 4. Time on dialysis = >90 days IDENTIFICATION OF NUMERATOR CASES Include in the numerator all patients from the denominator who meet the following criteria:	numerator and denominator is described below. The denominator will include all patients at least 18 years old who are determined to be maintenance hemodialysis patients. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patient months in the denominator who were on maintenance hemodialysis with a		

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	1. Access type = Functional autogenous AVF (defined as 2 needles used or single-needle device) (NOTE: 1 needle used in a 2-needle device is NOT acceptable) OR 1. Access type = Functional AV graft OR 1. Access type = AVF combined with AV graft OR 1. Access type (select one): • AV fistula with a catheter • AV graft combined with a catheter • Catheter • Other/unknown AND 2. Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period AND 3. Patient seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the	chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month. For CROWNWeb data, the numerator is defined as "Access_Type_id" in (19,20) while "19" means Catheter only and "20" means Port access only AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month. For Claims data, we use data prior to reporting period, a 90 day lookback period (e.g. October – December 2012 for January 2013 reporting period) to determine catheter history AND vascular access type should satisfy (vas_cat='Y' and art_graft=' ' and art_fistula=' ')). No diagram provided		

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	primary placement of vascular access for an AVF or AV graft during the 12-month reporting period AND 4. Facility medical records contain the following types of documentation of the surgical evaluation: • A note or letter prepared by the primary nephrologist OR • A note or letter prepared by the vascular surgeon, other qualified surgeon, or interventional nephrologist trained in the primary placement of vascular access OR • A note prepared by facility personnel AND • Date of the surgical evaluation: (MM/YYYY) AND • If permanent access was not placed, the reason for this decision MEASURE SCORE CALCULATION Performance Rate = ([Patients with a functional AVF] + [Patients with a functional AV graft] + [Patients with a catheter who have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or			

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	interventional nephrologist trained in the primary placement of vascular access for a functional AVF or AV graft during the 12-month reporting period WITH documentation of the evaluation in the facility medical records]) ÷ ([Total ESRD patients >/=18 years of age receiving HD during the 12-month reporting period and on dialysis >90 days] – Patients enrolled in hospice]) Available in attached appendix at A.1			
Submission items	5.1 Identified measures: 0256: Minimizing Use of Catheters as Chronic Dialysis Access 0257: Maximizing Placement of Arterial Venous Fistula (AVF) 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: NQF 0256 and 0257 focus on reducing catheter use exclusively in favor of AVF use. This construct ignores and thus disincentivizes use of AV grafts, which are oftentimes the most clinically appropriate access and are selected with and in the best interest of the patient, and may ultimately have a negative clinical impact.	5.1 Identified measures: 5a.1 Are specs completely harmonized? 5a.2 If not completely harmonized, identify difference, rationale, impact: 5b.1 If competing, why superior or rationale for additive value:	5.1 Identified measures: 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement 2594 : Optimal End Stage Renal Disease (ESRD) Starts 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components in addition to assessing fistula use. It is a referral process measure. The most basic requirement to get into the numerator is referral to a vascular surgeon (or other qualified physician). This has the potential for facilities to score well on the measure separate from whether patients are receiving treatment	5.1 Identified measures: 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement 2594 : Optimal End Stage Renal Disease (ESRD) Starts 5a.1 Are specs completely harmonized? No 5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components including AV fistula use, AV graft use or referral to a vascular surgeon (or other qualified physician) if using a long-term catheter. It is a referral process measure for those patients with a catheter. This has the potential for facilities to score well on the measure even if they have patients with a catheter, as

	0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	0256: Minimizing Use of Catheters as Chronic Dialysis Access	2977: Hemodialysis Vascular Access: Standardized Fistula Rate	2978: Hemodialysis Vascular Access: Long-term Catheter Rate
	5b.1 If competing, why superior or rationale for additive value: The KCQA measure acknowledges that AV grafts are frequently an appropriate clinical decision while continuing to disincentivize use of central venous catheters. Additionally, the measure is specified for use at the clinician, rather than the facility, level, as the clinical responsibility for vascular access decisionmaking lies primarily with the physician.		with a fistula, graft, or catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of this fistula measure to function as a more direct incentive to encourage fistula use. Moreover, consistent with the concerns and recommendations made by the vascular access TEP, the SFR is risk adjusted and includes risk factors to account for patients where fistula may not be the appropriate access type. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the SFR includes both incident and prevalent patients as the measured population. 5b.1 If competing, why superior or rationale for additive value: There are no competing measures.	with a fistula, graft, or catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of the catheter measure to function as a more direct disincentive to prolonged catheter use, consistent with the concerns and recommendations made by the vascular access TEP. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on prolonged catheter use. These suggest fundamental differences in measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the long-term catheter rate measure includes both incident and prevalent patients as the measured population. 5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

Appendix F2: Related and Competing Measures (Narrative Format)

Comparison of NQF 0251, NQF 0256, NQF 2977, and NQF 2978

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
0256: Minimizing Use of Catheters as Chronic Dialysis Access
2977: Hemodialysis Vascular Access: Standardized Fistula Rate
2978: Hemodialysis Vascular Access: Long-term Catheter Rate

Steward

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Kidney Care Qualuty Alliance (KCQA)

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Centers for Medicare & Medicaid Services

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Centers for Medicare & Medicaid Services

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Centers for Medicare & Medicaid Services

Description

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation 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 autogenous AVF (defined as two needles used or a single-needle device]) (computed and reported separately);

2. have a functional AV graft (computed and reported separately); 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 versus prevalent patients, as defined by USRDS.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Percentage of patient months on maintenance hemodialysis during the last HD treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

Type

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Process

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Outcome

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Intermediate Clinical Outcome

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Intermediate Clinical Outcome

Data Source

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records Data elements for the measure can be collected via the CROWNWeb Electronic Data Interchange, available at URL: http://www.projectcrownweb.org/crown/index.php.

No data collection instrument provided Attachment KCQA0251_DataDictionary02-26-15.pdf

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Administrative claims, Electronic Clinical Data CROWNWeb is the primary data source. However, this measure can be collected through Medicare claims data (since July 2010) and Fistula First Breakthrough Initiative data (though the definition of the measure is slightly different). The measure has been publically reported using claims data since 2013.

No data collection instrument provided No data dictionary

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Administrative claims, Electronic Clinical Data CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims and the CMS Medical Evidence form 2728 are data sources for the risk adjustment factors. Medicare claims and CROWNWeb are used for the exclusion criteria.

No data collection instrument provided Attachment 2977_Data_Dictionary_Code_Table.xlsx

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Administrative claims, Electronic Clinical Data CROWNWeb, Medicare Claims and the CMS Medical Evidence form 2728 are used as the data sources for establishing the

denominator. CROWNWeb is the data source for establishing the numerator. Medicare claims are used for the comorbidity conditions exclusion criteria.

No data collection instrument provided Attachment 2978_Data_Dictionary_Code_Table.xlsx

Level

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Clinician : Individual

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Facility

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Facility

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Facility

Setting

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Ambulatory Care : Clinician Office/Clinic, Dialysis Facility

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Dialysis Facility

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Dialysis Facility

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Dialysis Facility

Numerator Statement

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Number of patients from the denominator who:

1. have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or

2. have a functional AV graft (computed and reported separately); 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 (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).

Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Number of patient months in the denominator who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

Numerator Details

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Include in the numerator all patients from the denominator who meet the following criteria:

1. Access type = Functional autogenous AVF (defined as 2 needles used or single-needle device) (NOTE: 1 needle used in a 2-needle device is NOT acceptable)

OR

2. Access type =

• Functional AV graft OR

• AVF combined with AV graft OR

• Catheter (alone or combined with an AVF or AV graft)

AND

a. Patient 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 an AVF or AV graft during the 12-month reporting period

AND

b. Facility medical records contain the following types of documentation of the surgical evaluation:

• A note or letter prepared by the primary nephrologist OR

• A note or letter prepared by the vascular surgeon, other qualified surgeon, or interventional nephrologist trained in the primary placement of vascular access OR

• A note prepared by facility personnel

AND

• Date of the surgical evaluation: (MM/YYYY)

AND

• If permanent access was not placed, the reason for this decision.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Number of patient months in the denominator who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

The number of patient-months using an AVF as the sole means of vascular access at a given facility, adjusted for patient-mix.

An AVF is considered in use if the CROWNWeb "Access Type IDs" of 14 or 22 has been recorded for a given month, where "14" represents AV fistula only (with 2 needles) and "22" represents AV fistula only with an approved single needle device.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

The number of patient-months with a long-term catheter in use. Long-term catheter use is defined as using a catheter, at the same facility, for at least three consecutive complete months as of the last day of the reporting month.

For a given month, if any of the following CROWNWeb "Access Type IDs" (16,18,19,20,21,"·") has been recorded, a catheter is considered in use. If a catheter has been observed for three consecutive months (i.e., in the reporting month and the immediate two preceding months) at the same facility, the reporting month is counted in the numerator. Access Type ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing. If a patient changes dialysis facilities, the counting of the three consecutive complete months restarts at the new facility.

Denominator Statement

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.

This measure includes both in-center and home hemodialysis patients.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

The numerator will be determined by counting the patient-months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the entire reporting month at the same facility.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

Denominator Details

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice:

1. Diagnosis = ESRD

AND

2. Primary type of dialysis = hemodialysis or home hemodialysis

AND

3. Age = >/= 18 years

AND

4. Time on dialysis = >90 days

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Adult hemodialysis patients who have had ESRD for greater than 90 days as of of the first day of the reporting month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are on in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

For each patient, we identify the dialysis provider at each month using a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources are used to identify patients that are receiving in-center or home hemodialysis for the entire reporting month. Patients are required to have been treated by the same facility for the complete month in order to be assigned to that facility for the reporting month.

To be included in the denominator for a particular reporting month, the patient must be receiving home or in-center hemodialysis for the complete reporting month at the facility, and be at least 18 years old as of the first day of the month.

The monthly patient count at a facility includes all eligible prevalent and incident patients. The number of patient-months over a time period is the sum of patients reported for the

months covered by the time period. An individual patient may contribute up to 12 patient-months per year.

Exclusions

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

None.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.

For both CROWNWeb and Claims data, the denominator will include all hemodialysis patients who are at least 18 years old and have had ESRD for greater than 90 days as of the first day of the reporting month.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Exclusions that are implicit in the denominator definition include:

•Pediatric patients (<18 years old)

•Patients on Peritoneal Dialysis

•Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

•Patients under hospice care in the current reporting month

•Patients with metastatic cancer in the past 12 months

•Patients with end stage liver disease in the past 12 months

•Patients with coma or anoxic brain injury in the past 12 months

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Exclusions that are implicit in the denominator definition include:

-Pediatric patients (<18 years old)

-Patients on Peritoneal Dialysis

-Patient-months under in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

-Patients under hospice care in the current reporting month

-Patients with metastatic cancer in the past 12 months

-Patients with end stage liver disease in the past 12 months

-Patients with coma or anoxic brain injury in the past 12 months

Exclusion Details

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Not applicable.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old), and acute hemodialysis patients (hemodialysis patients who have had ESRD for less than 91 days). There are no additional exclusions for this measure.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are <18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claims. Medicare claim types include inpatient admissions, outpatient claims (including dialysis claims) and physician services. Claims from providers, such as laboratories that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file).

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Determination of peritoneal dialysis treatment modality is derived from a combination of Medicare-paid dialysis claims, the Medical Evidence Form (Form CMS-2728), and data from CROWNWeb. These sources also determine patient assignment to the facility. Patients not treated by the facility for the entire month are excluded for that reporting month.

The patient's age is determined by subtracting the patient's date of birth from the first day of the reporting month. Patients that are < 18 years old as of the first day of the reporting month are excluded.

For the exclusion of catheter patients with limited life expectancy, catheter use in the reporting month is defined as the CROWNWeb "Access Type ID" having any of the following values: (16,18,19,20,21,"·"), where Access_Type_ID "16" represents AV Fistula combined with a Catheter, "18" represents AV Graft combined with a Catheter, "19" represents Catheter only, "20" represents Port access only, "21" represents other/unknown, and "·" represents missing.

Hospice status is determined from a separate CMS file that contains final action claims submitted by Hospice providers. Once a beneficiary elects Hospice, all Hospice related claims will be found in this file, regardless if the beneficiary is in Medicare fee-for-service or in a Medicare managed care plan. Patients are identified as receiving hospice care if they have any final action claims submitted to Medicare by hospice providers in the current month.

Diagnoses of metastatic cancer, end stage liver disease, or coma in the past 12 months were determined from Medicare claim types. Medicare claims include inpatient hospitalizations, outpatient claims (including dialysis claims), and physician services. Claims from providers, such as laboratories, that report diagnosis codes when testing for the presence of a condition are excluded. A detailed list of ICD-9/ICD-10 diagnostic codes used to identify these comorbidities is included in the attached data dictionary code table (excel file).

Risk Adjustment

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

No risk adjustment or risk stratification

Not applicable.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

See above denominator details.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Statistical risk model

The proposed SFR measure is a directly standardized percentage, in that each facility's percentage of AVF use is adjusted to the national distribution of covariates (risk factors) (with 'national' here referring to all-facilities-combined). The SFR for facility i is an estimate of what the facility's percentage of AVF would equal if the facility's patient mix was equal to that of the nation as a whole. The measure is adjusted for patient demographic and clinical characteristics based on a logistic regression model. This model includes the facility indicators and assumes that the regression coefficients of risk factors are the same across all facilities. The common risk effects are assumed in order to improve computational stability in estimating facility-specific effects.

The patient characteristics included in the logistic regression model as covariates are:

•Age

•BMI at incidence

- Nursing home status in previous year
- Nephrologist's care prior to ESRD
- Duration of ESRD
- Inability to ambulate/transfer at ESRD incidence (CMS-2728 form)
- Comorbidities either at ESRD incidence (CMS-2728 form) or prevalent comorbidities based on Medicare claims filed in prior 12 months
  - Diabetes
  - Heart diseases
  - Peripheral vascular disease
  - Cerebrovascular disease
  - Chronic obstructive pulmonary disease
  - Anemia (unrelated to ESRD/CKD)
  - Non-Vascular Access-Related Infections
  - Drug dependence
- Indicator for Medicare coverage for at least 6 months during the past 12 months

Available in attached Excel or csv file at S.2b

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

No risk adjustment or risk stratification

N/A

Stratification

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Not applicable.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

No risk adjustment or risk stratification

N/A

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

N/A

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

N/A

Type Score

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

Rate/proportion better quality = higher score

0256: Minimizing Use of Catheters as Chronic Dialysis Access

N/A

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Rate/proportion better quality = higher score

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Rate/proportion better quality = lower score

Algorithm

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

The measure score is calculated by dividing the total number of patients included in the numerator by the total number of patients included in the denominator.

IDENTIFICATION OF DENOMINATOR CASES

To identify patients in the denominator, first calculate the following:

• Patient age = (Date of first day of most recent month of study period)—(Patient's Date of Birth)

• Patient time on dialysis = (Date of first day of most recent month of study period)—(Patient's Date Regular Chronic Dialysis Began)

Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice:

1. Diagnosis = ESRD

AND

2. Primary type of dialysis = hemodialysis or home hemodialysis

AND

3. Age = >/=18 years

AND

4. Time on dialysis = >90 days

IDENTIFICATION OF NUMERATOR CASES

Include in the numerator all patients from the denominator who meet the following criteria:

1. Access type = Functional autogenous AVF (defined as 2 needles used or single-needle device) (NOTE: 1 needle used in a 2-needle device is NOT acceptable)

OR

1. Access type = Functional AV graft

OR

1. Access type = AVF combined with AV graft

OR

1. Access type (select one):

• AV fistula with a catheter

• AV graft combined with a catheter

• Catheter

• Other/unknown

AND

2. Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period

AND

3. Patient 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 an AVF or AV graft during the 12-month reporting period

AND

4. Facility medical records contain the following types of documentation of the surgical evaluation:

• A note or letter prepared by the primary nephrologist OR

• A note or letter prepared by the vascular surgeon, other qualified surgeon, or interventional nephrologist trained in the primary placement of vascular access OR

• A note prepared by facility personnel

AND

• Date of the surgical evaluation: (MM/YYYY)

AND

• If permanent access was not placed, the reason for this decision

MEASURE SCORE CALCULATION

Performance Rate = ([Patients with a functional AVF] + [Patients with a functional AV graft] + [Patients with a catheter who 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 AVF or AV graft during the 12-month reporting period WITH documentation of the evaluation in the facility medical records]) ÷ ([Total ESRD patients >/=18 years of age receiving HD during the 12-month reporting period and on dialysis >90 days] – Patients enrolled in hospice]) Available in attached appendix at A.1

0256: Minimizing Use of Catheters as Chronic Dialysis Access

Rate/proportion better quality = lower score

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

See calculation flowchart in Appendix. Available in attached appendix at A.1

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

See calculation flowchart in Appendix. Available in attached appendix at A.1

Submission Items

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

5.1 Identified measures: 0256 : Minimizing Use of Catheters as Chronic Dialysis Access

0257 : Maximizing Placement of Arterial Venous Fistula (AVF)

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: NQF 0256 and 0257 focus on reducing catheter use exclusively in favor of AVF use. This construct ignores

and thus disincentivizes use of AV grafts, which are oftentimes the most clinically appropriate access and are selected with and in the best interest of the patient, and may ultimately have a negative clinical impact.

5b.1 If competing, why superior or rationale for additive value: The KCQA measure acknowledges that AV grafts are frequently an appropriate clinical decision while continuing to disincentivize use of central venous catheters. Additionally, the measure is specified for use at the clinician, rather than the facility, level, as the clinical responsibility for vascular access decisionmaking lies primarily with the physician.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

For this measure calculation, the numerator will be divided by the denominator.Calculation of the numerator and denominator is described below.

The denominator will include all patients at least 18 years old who are determined to be maintenance hemodialysis patients.

The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.

Hemodialysis patients are defined as follows: "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" ='Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.

The numerator will be determined by counting the patient months in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month.

For CROWNWeb data, the numerator is defined as "Access_Type_id" in (19,20) while "19" means Catheter only and "20" means Port access only AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month.

For Claims data, we use data prior to reporting period, a 90 day lookback period (e.g. October – December 2012 for January 2013 reporting period) to determine catheter history AND vascular access type should satisfy (vas_cat='Y' and art_graft=' ' and art_fistula=' ')). No diagram provided

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

5.1 Identified measures: 0251 : Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

2594 : Optimal End Stage Renal Disease (ESRD) Starts

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components in addition to assessing fistula use. It is a referral process measure. The most basic requirement to get into the numerator is referral to a vascular surgeon (or other qualified physician). This has the potential for facilities to score well on the measure separate from whether patients are receiving treatment with a fistula, graft,

or catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of this fistula measure to function as a more direct incentive to encourage fistula use. Moreover, consistent with the concerns and recommendations made by the vascular access TEP, the SFR is risk adjusted and includes risk factors to account for patients where fistula may not be the appropriate access type. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the SFR includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

5.1 Identified measures: 0251 : Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

2594 : Optimal End Stage Renal Disease (ESRD) Starts

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components including AV fistula use, AV graft use or referral to a vascular surgeon (or other qualified physician) if using a long-term catheter. It is a referral process measure for those patients with a catheter. This has the potential for facilities to score well on the measure even if they have patients with a catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of the catheter measure to function as a more direct disincentive to prolonged catheter use, consistent with the concerns and recommendations made by the vascular access TEP. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on prolonged catheter use. These suggest fundamental differences in measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the long-term catheter rate measure includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

5.1 Identified measures: 0256: Minimizing Use of Catheters as Chronic Dialysis Access

0257: Maximizing Placement of Arterial Venous Fistula (AVF)

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: NQF 0256 and 0257 focus on reducing catheter use exclusively in favor of AVF use. This construct ignores and thus disincentivizes use of AV grafts, which are oftentimes the most clinically appropriate access and are selected with and in the best interest of the patient, and may ultimately have a negative clinical impact.

5b.1 If competing, why superior or rationale for additive value: The KCQA measure acknowledges that AV grafts are frequently an appropriate clinical decision while continuing to disincentivize use of central venous catheters. Additionally, the measure is specified for use at the clinician, rather than the facility, level, as the clinical responsibility for vascular access decisionmaking lies primarily with the physician.

0256: Minimizing Use of Catheters as Chronic Dialysis Access

5.1 Identified measures:

5a.1 Are specs completely harmonized?

5a.2 If not completely harmonized, identify difference, rationale, impact:

5b.1 If competing, why superior or rationale for additive value:

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

5.1 Identified measures: 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

2594: Optimal End Stage Renal Disease (ESRD) Starts

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components in addition to assessing fistula use. It is a referral process measure. The most basic requirement to get into the numerator is referral to a vascular surgeon (or other qualified physician). This has the potential for facilities to score well on the measure separate from whether patients are receiving treatment with a fistula, graft, or catheter, as long as the patient was referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of this fistula measure to function as a more direct incentive to encourage fistula use. Moreover, consistent with the concerns and recommendations made by the vascular access TEP, the SFR is risk adjusted and includes risk factors to account for patients where fistula may not be the appropriate access type. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on fistula use. This suggests a fundamental difference in the measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the SFR includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

5.1 Identified measures: 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

2594: Optimal End Stage Renal Disease (ESRD) Starts

5a.1 Are specs completely harmonized? No

5a.2 If not completely harmonized, identify difference, rationale, impact: Measure 0251 contains several components including AV fistula use, AV graft use or referral to a vascular surgeon (or other qualified physician) if using a long-term catheter. It is a referral process measure for those patients with a catheter. This has the potential for facilities to score well on the measure even if they have patients with a catheter, as long as the patient was

referred to or evaluated by a vascular surgeon. We acknowledge this is an important step to fistula placement however it departs from the intent of the catheter measure to function as a more direct disincentive to prolonged catheter use, consistent with the concerns and recommendations made by the vascular access TEP. Measure 2594 is not directed toward dialysis facilities. The setting focus addresses a different provider type which falls outside the purview of measures evaluating dialysis facility performance on prolonged catheter use. These suggest fundamental differences in measure target populations, setting and intent that cannot be harmonized. Additionally, the measure is limited to incident patients, while the long-term catheter rate measure includes both incident and prevalent patients as the measured population.

5b.1 If competing, why superior or rationale for additive value: There are no competing measures.

Appendix G: Pre-Evaluation Comments

Comments received as of June 13, 2016.

0260: Assessment of Health-Related Quality of Life in Dialysis Patients

Lisa McGonigal, MD, MPH
Kidney Care Partners

KCP recognizes the importance of assessing the health-related quality of life for individuals with ESRD. Nevertheless we have an overarching concern about the measure, as well as specific concerns about the new specifications, evidence, performance gap, and validity.

OVERARCHING ISSUE. Annual administration of the KDQOL is already required by Federal regulation, the Conditions for Coverage. KCP questions how endorsement of a measure for a process that is already mandated and surveyed will further improve patient care.

SPECIFICATIONS. We support the changes to the exclusions that align them with the Conditions for Coverage, but KCP opposes eliminating the exclusion for patient refusal. First, the Conditions for Coverage permit patient refusal as long as it is documented. We believe approving a measure that directly conflicts with Federal regulation is problematic. Second, not accepting patient decisionmaking ignores patient autonomy; providers should not be forced to face intruding on patient decisionmaking vs. facing a penalty for poorer performance on this measure. We further note there is no performance gap when the specifications include patient refusal.

EVIDENCE. As noted, KCP recognizes the importance of assessing health-related quality of life, but questions the lack of direct evidence for the measure. The developer cites KDOQI and the Institute of Medicine on the importance of functional assessment, however no peer-reviewed, empirical evidence is provided that the specifications (i.e., annual completion rate) are associated with higher quality.

PERFORMANCE GAP. Based on the updated specifications, the performance range in 2015 was 16.7%-100%, with a median of 91.8% using "KDQOL-Complete" (K-C) data. Although the performance rate at the patient-level with the updated exclusion criteria (i.e., refusals = fail) is 84.8% (2015), 84.7% (2014), and 84.2% (2013), the performance rate with refusals as an exclusion (old specifications) is 100% in 2013, 2014, 2015. KCP also further examined the data and notes the refusal exclusion appears stable over this period. We posit the change in specifications creates a gap where otherwise none exists, as well as puts the measure in conflict with the Conditions for Coverage.

0260: Assessment of Health-Related Quality of Life in Dialysis Patients

Lisa McGonigal, MD, MPH
Kidney Care Partners

VALIDITY. KCP has two concerns about the measure's validity: the validity testing and the lack of risk adjustment.

The developer performed validity testing on a sample that included all patients—i.e., those who refused, those who completed the survey, and those who met the exclusion criteria. It assessed association of completion with patients' KDQOL scores (linear fixed models with the score for each of the five scales as the dependent variable and facility completion rate as the main independent variable). The models adjusted for patient-level characteristics of age, gender, race, and diabetes. Based on this, it appears the measure was not tested as specified. First, all patients were used, even those who qualify for exclusions. Second, associations were examined, but the models were adjusted for patient-level characteristics even though the measure itself is not adjusted. Performance on the measure cannot be asserted as being associated with better quality (the five KDQOL scales) if the measure as specified is not used.

The developer also notes, "This finding [association between completion and scores] is important because it is plausible that facilities with higher rates would be obtaining completed questionnaires from sicker patients, since it has been documented that individuals completing the QoL scores tend to be younger and healthier." Again, the developer draws this conclusion from analyzing a different data set and a risk-adjusted model. The measure is not whether an all-population, risk-adjusted measure of completion validates against the scale results: Testing and demonstration of validity must be of the measure as specified.

Finally, KCP has expressed concern about NQF 0260 in other contexts (e.g., use in CMS' Comprehensive ESRD Care Initiative) because of the lack of risk adjustment for case mix. In fact, the developer's data demonstrate that case mix impacts a facility's score. Specifically, the developer presents data on the distribution of patient characteristics and the facility-level survey completion rate; the analysis uses refusals and completions, so comports with the proposed specifications. Facilities with more males will score, on average, 0.45% lower (per 10% difference) compared to facilities that have fewer males. Conversely, facilities with higher proportions of Asians—likely to exist in certain geographic areas—will score higher. We believe the lack of adjustment for the measure presents a significant threat to validity, particularly given a median performance of 91.8% with the updated specifications.

0369: Standardized Mortality Ratio for Dialysis Facilities

Daniel E. Weiner, MD, MS
Dialysis Clinic, Inc

I appreciate the opportunity to comment on NQF 0369 and NQF 1463, the Risk-Adjusted SMR and SHR. These are important outcome measures and the use of risk adjustment for comorbid conditions based on claims data is an important advance. The adjustment methodology has important validity issues.

Model selection needs to incorporate background knowledge about the relationship of a variable to the outcome of interest. Unfortunately, adjustment for prevalent comorbid conditions proposed in these metrics relied almost entirely on automatic variable selection techniques, resulting in a model that may be robust only for the data on which it was generated and that will rapidly lose validity as coders and codes change. In defending the methodology, the developer stated that the TEP agreed with the

inclusion of this set of prevalent comorbidities. In discussing with TEP members, this is misleading, with members noting the same concerns as raised in this letter about the final models.

Examples include:

1. Cancer is good. The constellation of prostate, thyroid, and kidney cancer together has twice the protective effect against death that gangrene has for harm. This of course is ridiculous; however, the coefficients generated for these comorbid coefficients reflect multicollinearity among variables; coding habits; survival, indication and lead time biases; and, critically, lack of incorporation of existing knowledge into the predictive modeling approach.

2. Peripheral vascular disease codes for important conditions like gangrene, ulcers and osteomyelitis are messy, with numerous positive and negative coefficients that are likely to deviate from the truth with each passing year as coding habits change, providing a classic example of the pitfalls of multicollinearity in predictive models.

3. Codes for diabetic eye disease are highly protective. Why? Likely because these codes indicate that a dialysis patient has seen an ophthalmologist, which is likely an indicator of care coordination. Inclusion of these 3 variables will harm ESCOs for example, where an eye exam is a process measure. This makes no physiologic sense.

The examples above illustrate where, although statistically correct at the time of model development, the adjustment process is destined to lose robustness rapidly with time.

In evaluating these proposed measures, I hope NQF calls attention to the details of the adjustment model and suggests a refined approach moving forward that incorporates both the advanced statistical techniques that were used in the proposed model along with existing knowledge on the relationships of clinical conditions with outcomes and awareness of the biases inherent in the use of these administrative data to develop future comorbidity adjustment models that will remain robust for their intended purpose.

0369: Standardized Mortality Ratio for Dialysis Facilities

Joseph Vassalotti, MD
National Kidney Foundation

Per our comments to the Measures Application Partnership (MAP), the National Kidney Foundation (NKF) does not support this measure as it does not clearly encourage quality improvement nor provide meaningful information to patients. This measure does not stratify by causes of mortality that are attributable to the care that a patient receives by the dialysis care team and does not adequately adjust for comorbidities. For example, clinics caring for patients with high levels of comorbidity, poor functional status and frailty will be penalized. This may create disincentives to accept patients with complex illness. In addition and as the MAP recommended, patients who begin dialysis while in hospice should be excluded from the measure. Some patients may elect to begin dialysis while under hospice before later deciding to discontinue. This is a difficult decision for patients and families and should not

be unintentionally discouraged by including these patients in the SMR. Lastly, patients acknowledge concern about dialysis units that have high SMRs, but do not have enough information to interpret SMR as it reflects quality dialysis care delivery.

0369: Standardized Mortality Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

KCP believes mortality is an important outcome to measure, but has concerns about the specifications, reliability, validity (risk model), and harmonization issues.

SPECIFICATIONS. The specifications for the time period state "at least one year." KCP believes specifications should be unambiguous, so this construction is imprecise. We believe the time period should be an exact period, and we further believe the 1-year period is inappropriate based on the reliability testing data and, at minimum, should be a 4-year period.

As we discuss further in the following section, KCP has significant concerns about the SMR's reliability for small- and medium-sized facilities. The SMR specifications do not address a minimum sample size by excluding facilities of "x" or fewer patients, as we are aware other measures do.

The specifications do not exclude incident hospice patients. The NQF's Measure Applications Partnership (MAP) recently did not recommend the SMR, in part because the measure did not exclude patients who are already in hospice when they initiate dialysis. During the deliberations, it was noted that occasionally incident patients begin dialysis treatments while in hospice, but then choose to discontinue them after a period of time. KCP supports MAP's recommendation that patients who initiate dialysis while also in hospice be excluded from the SMR. As currently constructed, such patients are attributed to the facility providing the dialysis.

The SMR documentation indicates at least three expected deaths must occur for inclusion in the SMR calculations, but no justification or empirical analyses are offered to justify this threshold—e.g., how many clinics were excluded using this approach and what is the impact on scoring because of the exclusion?

Finally, the SMR specifications indicate the measures can be expressed as a rate, but is calculated as a ratio. KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid rate methodology. We note that MAP also did not support the SMR because, in addition to the lack of a hospice exclusion, MAP felt "mortality rates would be more meaningful to consumers and actionable for facilities."

0369: Standardized Mortality Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

RELIABILITY. Based on the testing results, KCP has serious concerns about the SMR's reliability. We note a reliability statistic of 0.70 is often considered as "good" reliability,[1] though we recognize the characterization also depends on the analytic method. Testing results for the 1-year SMR yielded IURs of 0.26-0.32 for each of 2010, 2011, 2012, and 2013—a low degree of reliability, where only about 30% of the variation in a score can be attributed to between-facility differences, yet the specifications permit this 1-year measure. The 4-year SMR yielded an IUR of 0.66 for 2009-2012 and only 0.59 for 2010-2013 data. Even with the 4-year SMR, less than 60% of a facility's score is attributable to between-facility differences for the overall sample. Moreover, 4-year SMR testing results specifically for small- and medium-sized facilities indicate very poor reliability, with IURs of 0.30 and 0.45, respectively. Only large facilities have a reasonable IUR of 0.73 for 2010-2013 data. As noted earlier, KCP thus believes the specifications must specifically require a minimum sample as identified through the developer's empirical testing.

VALIDITY. KCP has strongly advocated for the use of prevalent co-morbidities in the SMR's risk model, and commends the developer for moving to incorporate prevalent co-morbidities in the specifications. We continue to be concerned about the validity of the Medical Evidence Form (CMS 2728) as a data source for incident co-morbidities, however, and urge that the Committee recommend that CMS assess this matter.

In previous comments to CMS, KCP noted that many of the prevalent co-morbidities in the final model had p-values significantly greater than 0.05—e.g., paralytic ileus (p=0.5007), episodic mood disorder NOS (p=0.8254). CMS responded that these were included because: "Most of the coefficient estimates for the prevalent co-morbidities are positive and statistically significant, but several do not obtain statistical significance. The very large number of clinical factors in the model expectedly generates multi-collinearity among co-variates, likely resulting in some unexpected results in direction of coefficient sign and levels of statistical significance. Inclusion of this set of prevalent co-morbidities reflects the consensus of the TEP that adjustment for all of these prevalent co-morbidities, in addition to incident co-morbidities, is important to reflect the initial and current health condition of the patient in risk adjustment."

[1]Adams, JL. The Reliability of Provider Profiling: A Tutorial. Santa Monica, California:RAND Corporation. TR-653-NCQA, 2009.

0369: Standardized Mortality Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

VALIDITY (cont.). We do not believe this approach is sufficient. Our conversations with TEP members for the SMR/SHR indicate they did not advocate for model building in a vacuum without accounting for

the meaning of the coded co-morbid conditions, but rather for including as many co-morbid conditions as possible. This is a very different interpretation than is offered by the developer's explanation and far more appropriate when dealing with administrative coding habits that are not static over time. It may require, for example, grouping certain individual codes together to develop a more appropriate overarching description of true co-morbidity burden.

KCP is concerned that the strategy adopted for the SMR (and SHR) results in a model that will not be generalizable. Currently, for example, having thyroid cancer is protective to the same magnitude that atrial fibrillation is harmful. This makes no sense, and we posit is a function of collinearity and coding idiosyncrasy. Similarly, in the current model, osteomyelitis NOS-ankle is associated with a lower risk of death while ulcer of lower limb NOS is harmful. In actual medical practice, osteomyelitis is far worse than an ulcer of the lower limb. In the current model, lower extremity amputation is protective while 'status amput below knee' is harmful. Again, KCP supports prevalent co-morbidity adjustment, but we are concerned that the proposed collection of adjusters will be less robust with each year that passes from initial model development.

KCP also notes that while the SMR applies to all patients, the current list of co-morbidities does not account for those that may be unique to pediatrics. We recommend the Standing Committee suggest to the developer that such should be considered and included when indicated.

KCP also notes that the validity testing yielded a c-statistic for the SMR of 0.724. We are concerned the model will not adequately discriminate performance—particularly that smaller units, including pediatric units, might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model.

0369: Standardized Mortality Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

VALIDITY (cont.). Information on the risk model states that determination of a prevalent co-morbidity requires at least two outpatient claims or one inpatient claim, but no justification or empirical analyses are offered to support this algorithm over other approaches. We are aware this approach has been validated for diabetes,[2] but we are not that it has been validated for the large number of other co-morbidities or is broadly generalizable.

Finally, the risk model includes ambiguous language. The submission indicates patient characteristics included in the stage 1 model include "nursing home status in previous year." It is unclear if this means patients moving into a nursing home for the first time during the measurement year would not be adjusted for "nursing home status." Specifically, it is unclear as to whether the look-back is one year prior to the given event (inclusive of the data year) or if this verbiage means the look-back is in the previous calendar year (not inclusive of the data year). KCP believes such ambiguity should be addressed and that the current reporting year be included, not just the previous one.

HARMONIZATION ISSUES. The risk models for the groupings used for patient age and duration of ESRD differ among the SMR, SHR, and STrR. For example, the age groups for the SMR is n=3, but for the SHR and STrR the age groupings are the same, but n=6. Similarly, the number of groups for ESRD duration for the SMR (n=4) differs from that for the SHR (n=6). No justification or empirical analyses are offered to justify these differences.

There also are significant inconsistencies in how facility size is defined when assessing reliability for the SMR, SHR, and STrR. Specifically, for the SMR, the definitions were <=45, 46-85, >=86 for the 1-year reliability analyses, but were <=135, 136-305, and >=306 for the 4-year analyses. For the SHR, <=50, 51-87, and >=88 were used. Finally, for STrR reliability analyses, small, medium, and large facilities were defined as <=46, 47-78, and >=79, respectively. We understand reliability for a given measure depends on sample size, but find the varying demarcations analytically troubling. We posit a more appropriate analytic approach would be to analyze reliability using consistent "bins" of size (i.e., small, medium, and large are consistently defined) and identify the facility size at which reliability for that particular measure can be confidently inferred—and then reflect the minimum size in the actual specifications.

[2]Hebert PL, Geiss LS, et al. Identifying persons with diabetes using Medicare claims data. Am J Med Qual. 1999;14(4):270-277.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

Daniel E. Weiner, MD, MS
Dialysis Clinic, Inc. (DCI)

I appreciate the opportunity to comment on NQF 0369 and NQF 1463, the Risk-Adjusted SMR and SHR. These are important outcome measures and the use of risk adjustment for comorbid conditions based on claims data is an important advance. The adjustment methodology has important validity issues.

Model selection needs to incorporate background knowledge about the relationship of a variable to the outcome of interest. Unfortunately, adjustment for prevalent comorbid conditions proposed in these metrics relied almost entirely on automatic variable selection techniques, resulting in a model that may be robust only for the data on which it was generated and that will rapidly lose validity as coders and codes change. In defending the methodology, the developer stated that the TEP agreed with the inclusion of this set of prevalent comorbidities. In discussing with TEP members, this is misleading, with members noting the same concerns as raised in this letter about the final models.

Examples include:

1. Cancer is good. The constellation of prostate, thyroid, and kidney cancer together has twice the protective effect against death that gangrene has for harm. This of course is ridiculous; however, the coefficients generated for these comorbid coefficients reflect multicollinearity among variables; coding habits; survival, indication and lead time biases; and, critically, lack of incorporation of existing knowledge into the predictive modeling approach.

2. Peripheral vascular disease codes for important conditions like gangrene, ulcers and osteomyelitis are messy, with numerous positive and negative coefficients that are likely to deviate from the truth with each passing year as coding habits change, providing a classic example of the pitfalls of multicollinearity in predictive models.

3. Codes for diabetic eye disease are highly protective. Why? Likely because these codes indicate that a dialysis patient has seen an ophthalmologist, which is likely an indicator of care coordination. Inclusion of these 3 variables will harm ESCOs for example, where an eye exam is a process measure. This makes no physiologic sense.

The examples above illustrate where, although statistically correct at the time of model development, the adjustment process is destined to lose robustness rapidly with time.

In evaluating these proposed measures, I hope NQF calls attention to the details of the adjustment model and suggests a refined approach moving forward that incorporates both the advanced statistical techniques that were used in the proposed model along with existing knowledge on the relationships of clinical conditions with outcomes and awareness of the biases inherent in the use of these administrative data to develop future comorbidity adjustment models that will remain robust for their intended purpose.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

KCP believes hospitalization is an important outcome to measure, but has concerns about the specifications, reliability, validity (risk model), and harmonization issues. Many of our comments have been articulated in the context of those we make on the SMR, but owing to the NQF's electronic portal for measure-by-measure comments, we repeat them for the SHR.

SPECIFICATIONS. KCP has strongly advocated for the use of prevalent co-morbidities in the SHR's risk model, and commends the developer for moving to incorporate prevalent co-morbidities in the specifications. We continue to be concerned about the validity of the Medical Evidence Form (CMS 2728) as a data source for incident co-morbidities, however, and urge that the Committee recommend that CMS assess this matter.

The SHR specifications for the time period also state "at least one year." Again, as a principle, KCP believes specifications should be unambiguous. We believe the time period should be an exact period.

As we discuss in the reliability section, KCP has significant concerns about the reliability of the 1-year SHR for small and medium facilities. The SHR specifications do not address a minimum sample size by excluding facilities of "x" or fewer patients, as we are aware other measures do.

Documentation indicates the minimum data requirement for the SHR is 5 patient-years at risk, which differs from the STrR, which uses 10 patient-years at risk. No justification or empirical analyses are offered to justify the selected threshold or the difference.

Finally, the SHR specifications indicate the measure can be expressed as a rate, but is calculated as a ratio. KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid rate methodology.

RELIABILITY. We again note a reliability statistic of 0.70 is often considered as "good" reliability, though we recognize the characterization also depends on the analytic method. Again, based on the results from the reliability testing, we have significant concerns about the reliability of the 1-year SHR for small and medium facilities (IUR range of 0.46-0.65, depending on the year). The SHR specifications do not address a minimum sample size by excluding facilities of "x" or fewer patients, as we are aware other measures do. As noted earlier, KCP thus believes the specifications must specifically require a minimum sample as identified through the developer's empirical testing.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

VALIDITY. KCP has strongly advocated for the use of prevalent co-morbidities in the SHR's risk model, and commends the developer for moving to incorporate prevalent co-morbidities in the specifications. We continue to be concerned about the validity of the 2728 as a data source for incident co-morbidities, however, and urge that the Committee recommend that CMS assess this matter.

In previous comments to CMS, KCP noted that many of the prevalent co-morbidities in the final model had p-values significantly greater than 0.05—e.g., paralytic ileus (p=0.5007), episodic mood disorder NOS (p=0.8254). CMS responded that these were included because: "Most of the coefficient estimates for the prevalent co-morbidities are positive and statistically significant, but several do not obtain statistical significance. The very large number of clinical factors in the model expectedly generates multi-collinearity among co-variates, likely resulting in some unexpected results in direction of coefficient sign and levels of statistical significance. Inclusion of this set of prevalent co-morbidities reflects the consensus of the TEP [Technical Expert Panel] that adjustment for all of these prevalent co-morbidities, in addition to incident co-morbidities, is important to reflect the initial and current health condition of the patient in risk adjustment."

We do not believe this approach is sufficient. Our conversations with TEP members indicate they did not advocate for model building in a vacuum without accounting for the meaning of the coded co-morbid conditions, but rather for including as many co-morbid conditions as possible. This is a very different interpretation than is offered by the developer's explanation and more appropriate when dealing with administrative coding habits that are not static over time. It may require, for example, grouping certain individual codes together to develop an appropriate overarching description of true co-morbidity burden.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

VALIDITY (cont.). KCP is concerned the strategy adopted for the SHR (and SMR) results in a model that will not be generalizable. Currently, for example, having thyroid cancer is protective to the same magnitude that atrial fibrillation is harmful. This makes no sense, and we posit is a function of collinearity and coding idiosyncracy. Similarly, in the current model osteomyelitis NOS-ankle is associated with a lower risk of death, while ulcer of lower limb NOS is harmful. In actual medical practice, osteomyelitis is far worse than an ulcer of the lower limb. In the current model, lower extremity amputation is protective while 'status amput below knee' is harmful. Again, KCP supports prevalent co-morbidity adjustment, but we are concerned that the proposed collection of adjusters will be less robust with each year that passes from initial model development.

KCP also notes that the validity testing yielded an overall c-statistic for the SHR of 0.65. We are concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model.

Information on the risk model states that determination of a prevalent co-morbidity requires at least two outpatient claims or one inpatient claim, but no justification or empirical analyses are offered to support this algorithm over other approaches. As noted for the SMR, we are aware this approach has been validated for diabetes, but we are not that it has been validated for the large number of other co-morbidities or is broadly generalizable.

Finally, the risk model includes ambiguous language. The submission indicates patient characteristics included in the stage 1 model include "nursing home status in previous year." It is unclear if this means patients moving into a nursing home for the first time during the measurement year would not be adjusted for "nursing home status." Specifically, it is unclear as to whether the look-back is one year prior to the given event (inclusive of the data year) or if this verbiage means the look-back is in the previous calendar year (not inclusive of the data year). KCP believes such ambiguity should be addressed and that the current reporting year be included, not just the previous one.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

HARMONIZATION ISSUES. The risk models for the groupings used for patient age and duration of ESRD differ among the SMR, SHR, and STrR. For example, the age groups for the SMR is n=3, but for the SHR and STrR the age groupings are the same, but n=6. Similarly, the number of groups for ESRD duration for the SMR (n=4) differs from that for the SHR (n=6). No justification or empirical analyses are offered to justify these differences.

There also are significant inconsistencies in how facility size is defined when assessing reliability for the SMR, SHR, and STrR. Specifically, for the SMR, the definitions were <=45, 46-85, >=86 for the 1-year reliability analyses, but were <=135, 136-305, and >=306 for the 4-year analyses. For the SHR, <=50, 51-87, and >=88 were used. Finally, for STrR reliability analyses, small, medium, and large facilities were defined as <=46, 47-78, and >=79, respectively. We understand reliability for a given measure depends on sample size, but find the varying demarcations analytically troubling. We posit a more appropriate analytic approach would be to analyze reliability using consistent "bins" of size (i.e., small, medium, and large are consistently defined) and identify the facility size at which reliability for that particular measure can be confidently inferred—and then reflect the minimum size in the actual specifications.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Joseph Vassalotti, MD
National Kidney Foundation

The National Kidney Foundation (NKF) strongly supports this measure and its pairing with the long-term catheter rate measure (NQF #2978). NKF is particularly pleased with the additional exclusions that acknowledge catheter use for patients with limited life expectancy. These changes align with NKF's previous recommendations.

We do note that clarity around sole access use would strengthen this measure. Specifically, credit for this measure should only apply if the patient does not have a catheter. As written it could be interpreted that the facility would get credit for a patent with a catheter as long as the catheter was not being used for dialysis. The presence of a catheter increases patients risk for infection and therefore no credit should be given if the patient has a catheter. In contrast if a patient has an AV graft that is not being used credit for the measures should still apply as the risk of AV graft infection is low, but there is associated risk with removal.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

Lisa McGonigal, MD, MPH
National Kidney Care Partners

As with the catheter measure, KCP used the existing arteriovenous fistula (AVF) measure, NQF 0257, for context in our review.

SPECIFICATIONS. The language in #0257 that specifically defines an autogenous AVF as using two needles has been replaced with an autogenous AVF "as the sole means of vascular access." KCP believes the specifications are imprecise as to whether facilities would receive credit for patients using an AVF as the sole means of access, but who also have in place a graft or catheter that is no longer being used. We note patients with catheters remain at risk for infection and other adverse sequellae, so credit should not be not given when a catheter is present, even if an AVF is being used. A numerator that specifies the patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present" would remove ambiguity. In contrast, removal of an AV graft is complex and not

without risk of complications, so KCP believes credit should be received for a patient who is using an AVF as the sole means of access, but who also may have a non-functioning AV graft present.

KCP notes the 90-day ESRD requirement has been removed from the denominator statement as compared to #0257, which means the "clock" for the measure starts on the first day of dialysis in a non-hospital setting—but that the permitted timeframe for catheter use in the numerator is still 90 days; we support this change. Additionally, we commend the developer for adding an exclusion for patients with limited life expectancy and for now unambiguously identifying the four subcategories, both approaches that KCP had recommended.

VALIDITY. KCP believes this measure improves on #0257 and commends the developer for accepting KCP's recommendation in previous comments to remove the co-variate alcohol dependence from the model's risk variables. We continue to believe two additional vasculature risk variables would strengthen the model: a history of multiple prior accesses and the presence of a cardiac device.

KCP notes that the validity testing yielded an overall c-statistic of 0.71. We are concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Joseph Vassalotti, MD
National Kidney Foundation

National Kidney Foundation (NKF) strongly supports this measure and its pairing with the standardized fistula rate measure (NQF #2977). NKF is particularly pleased with the four additional exclusions that acknowledge catheter use is appropriate for patients with limited life expectancy. These changes align with NKF's previous recommendations.

We do note that clarity around catheter use continuously would strengthen this measure. Specifically, the numerator should include all patients with a catheter in place for the reporting period, whether the hemodialysis catheter is in continuous use or not. The presence of a catheter increases the risk for infection even if it is not in use.

2978: Hemodialysis Vascular Access: Long-Term Catheter Rate

Lisa McGonigal, MD, MPH
Organization Kidney Care Partners

As with the AVF measure, KCP used the existing catheter measure, NQF 0256, for context in our review.

SPECIFICATIONS. As with the AVF measure, KCP notes the 90-day ESRD requirement has been removed from the denominator statement as compared to #0256, which means the "clock" for the measure starts on the first day of dialysis in a non-hospital setting—but that the permitted timeframe for

catheter use in the numerator is still 90 days; we support this change. Additionally, we commend the developer for adding an exclusion for patients with limited life expectancy and for now unambiguously identifying the four subcategories, both approaches that KCP had recommended.

2979: Standardized Transfusion Ratio for Dialysis Facilities

Joseph Vassalotti, MD
National Kidney Foundation

The National Kidney Foundation (NKF) believes that a transfusion avoidance measure is important to protecting patients from unnecessary transfusions. Risks of red blood cell transfusions in dialysis patients include hyperkalemia, volume overload and antigen sensitization for a potential future kidney transplant. However, a transfusion avoidance measure should be stratified to appropriately capture blood transfusions that could have been prevented by the dialysis facility and exclude other reasons for transfusions. To this end we appreciate the exclusions of certain patient populations that are likely to experience anemia and may require blood transfusions due to other comorbid conditions. NKF acknowledges tracking blood transfusion data are critical to understanding patient safety hazards. NKF also recognizes that since most blood transfusions are provided outside of the dialysis setting how transfusions are reported and submitted as claims to CMS may vary by hospital and by patient and this could cause variation in performance on the StR. NKF encourages CMS to explore ways to ensure hospitals appropriately report and standardize reporting on blood transfusions for dialysis patients.

2979: Standardized Transfusion Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

During the last project, this Standing Committee reviewed the STrR as #2699 and did not recommend it. As we discuss further in the section on Validity, we do not believe the new measure addresses the Committee's concerns about hospital- and physician-related factors. We comment on the specifications, reliability, validity (risk model), and harmonization issues.

SPECIFICATIONS. CMS has revised the measure specifications to more "conservatively" define transfusion events, such that all inpatient transfusion events must include, at a minimum, an appropriate ICD-9 Procedure Code or Value Code to be captured in the measure—inpatient transfusion events for claims that include only 038 or 039 revenue codes without an accompanying procedure or value code are not captured in the numerator. The specifications also specify a maximum of one event per day and that an event not be defined by the number of units of blood transfused.

KCP supports and appreciates the need to refine and tighten how transfusion events are counted and applauds CMS's intent in undertaking these revisions, but we do not believe the proposed solution is a valid representation of transfusion events. Importantly, there is no existing coding requirement that procedure or value codes be used, which means valid transfusion claims that include only revenue codes will be missed. KCP believes the proposed specification changes result in a measure with significant threats to validity.

Current transfusion coding practices clearly vary by hospital,[3] and hospital coding practices are beyond dialysis facilities' sphere of control. For example, we are aware of hospitals that exclusively use revenue codes and do not use the procedure or value codes. In-patients at this type of hospital will appear to have no transfusion events assigned to the dialysis facility, whereas those at a hospital that uses the procedure and/or value codes will have recorded events. Simply put, facilities within given catchment areas will be differentially affected by hospital coding variations, which clearly impact measure scoring. We are particularly concerned that the revisions, if implemented, will result in increased variability in performance across dialysis facilities wholly due to external factors and not performance. Facilities will appear to have "poor" performance because of higher than expected numbers of transfusions—and will expend time and resources to improve—when in fact the score is merely a reflection of coding practices.

[3]Weinhandl ED, Gilbertson DT, Collins AJ. Dialysis facility-level transfusion rates can be unreliable due to variability in hospital-level billing patterns for blood. Chronic Disease Research Group poster, ASN. 2014.

2979: Standardized Transfusion Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

SPECIFICATIONS (cont.). Again, KCP strongly supports the need to refine how transfusion events are defined, and we urge the Standing Committee to recommend the developer continue considering alternative models to define transfusion events. Alternatively, the Committee could suggest that CMS consider revising hospital transfusion coding rules to require that the ICD-9/ICD-10 procedure and value codes necessary for the validity of the proposed methodology be universally included in claims.

Additionally, the testing documentation notes that facilities with 10 or fewer patients were excluded, but we note the specifications do not state this. Again, KCP believes that a minimum size exclusion should be indicated and, as the developer's results document, and we discuss in the following section, reliability is poor even when the facility size is significantly greater than 10 patients.

The submission also indicates the minimum data requirement for the STrR is 10 patient-years at risk, which differs from the SHR, which uses 5 patient-years at risk. No justification or empirical analyses are offered to justify the selected threshold or the difference.

Finally, the STrR specifications indicate the measure can be expressed as a rate, but is calculated as a ratio. KCP prefers normalized rates or year-over-year improvement in rates instead of a standardized ratio. We believe comprehension, transparency, and utility to all stakeholders is superior with a scientifically valid rate methodology.

RELIABILITY. In addition to our concerns that the specifications pose a threat to the validity of the updated STrR, KCP also has concerns about the reliability testing for these revised specifications.

KCP again notes a reliability statistic of 0.70 is often considered as "good" reliability,though the characterization also depends on the analytic method. Reliability testing, overall, for the STrR yielded IURs of 0.60-0.66 across all facilities for each of 2011, 2012, 2013, and 2014. Such values indicate about 65% of the variation in a score can be attributed to between-facility differences (signal) and about 35% to within-facility differences (noise)—a moderate degree of reliability. However, when looking exclusively at small (defined as <=46) and medium (47-78) facilities, the IURs are substantially lower. Specifically, the IURs ranged from 0.30-0.41 and 0.50-0.56 for small and medium facilities, respectively, over the same time period. As noted earlier, KCP thus believes the specifications must specifically require a minimum sample as identified through the developer's empirical testing.

2979: Standardized Transfusion Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

VALIDITY. In addition to KCP's concerns about the specifications and the threat to validity of variable capture of transfusion events depending on hospital coding practices, KCP has several concerns about the co-variates (or lack thereof) and risk model.

NQF did not endorse the STrR in 2015, in part because this Standing Committee raised concern that the measure did not adjust for hospital- and physician-related transfusion practices. Physicians independently, or following hospital protocols, make decisions about whether or not to transfuse a specific patient, so it is important to account for the variability these factors create. The revised measure does not incorporate these factors into the risk model, so KCP's concurrence with the Committee's original concern remains.

KCP notes that while the SMR and SHR have been revised to incorporate prevalent co-morbidities into their risk models, the STrR has not been so revised; only incident co-morbidities, derived from the Medical Evidence Form (CMS 2728), are considered. This approach means the STrR risk model only reflects those conditions present upon when the patient initiates dialysis; failure to appropriately account for prevalent co-morbidities is a threat to validity. In the harmonization section, we also note that CMS adjusts for 2728-derived co-morbidities for SHR and SMR differently than it does for the STrR. Finally, as we have noted before, we continue to be concerned about the validity of the 2728 as a data source and urge that the Committee recommend that CMS assess this matter.

KCP notes that the validity testing yielded an overall c-statistic of 0.65. We are concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model.

2979: Standardized Transfusion Ratio for Dialysis Facilities

Lisa McGonigal, MD, MPH
Kidney Care Partners

HARMONIZATION ISSUES. The new SMR and SHR risk models adjust for each incident co-morbidity (from the 2728) separately, instead of using a "co-morbidity index." The model also approaches diabetes as a single co-morbidity rather than four separate indicators (currently on insulin, on oral medications, without medications, diabetic retinopathy). The STrR has not been similarly revised. KCP believes the Standing Committee should recommend that the developer harmonize the STrR with the other measures so that each incident co-morbidity is examined separately (i.e., unbundled, as compared to the current measure) and diabetes is approached as a single co-morbidity (i.e., bundled, as compared to the current risk model).

The risk models for the groupings used for patient age and duration of ESRD differ among the SMR, SHR, and STrR. For example, the age groups for the SMR is n=3, but for the SHR and STrR the age groupings are the same, but n=6. Similarly, the number of groups for ESRD duration for the SMR (n=4) differs from that for the SHR (n=6). No justification or empirical analyses are offered to justify these differences.

There also are significant inconsistencies in how facility size is defined when assessing reliability for the SMR, SHR, and STrR. Specifically, for the SMR, the definitions were <=45, 46-85, >=86 for the 1-year reliability analyses, but were <=135, 136-305, and >=306 for the 4-year analyses. For the SHR, <=50, 51-87, and >=88 were used. Finally, for STrR reliability analyses, small, medium, and large facilities were defined as <=46, 47-78, and >=79, respectively. We understand reliability for a given measure depends on sample size, but find the varying demarcations analytically troubling. We posit a more appropriate analytic approach would be to analyze reliability using consistent "bins" of size (i.e., small, medium, and large are consistently defined) and identify the facility size at which reliability for that particular measure can be confidently inferred—and then reflect the minimum size in the actual specifications.

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