

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

Purple text represents the responses from measure developers. Red text denotes developer information has changed since the last measure evaluation review. Some content in the document is from Measure Developers.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 2496

Measure Title: Standardized Readmission Ratio (SRR) for Dialysis Facilities

Measure Steward: Centers for Medicare & Medicaid Services

Brief Description of Measure: The Standardized Readmission Ratio (SRR) for a dialysis facility is the ratio of the number of observed index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm. Note that the measure is based on Medicare-covered dialysis patients.

Developer Rationale: Unplanned readmission rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and hospitalizations account for approximately 38% of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2018). In 2010, 37% of dialysis patient discharges from an all-cause hospitalization were followed by an unplanned readmission within 30 days (U.S. Renal Data System, 2018). Measures of the frequency of unplanned readmissions, such as SRR, help efforts to control escalating medical costs, play an important role in providing cost-effective health care, and support coordination of care across inpatient and outpatient settings. Preventive interventions such as fluid weight management, management of mineral and bone disease, anemia management as well as post-discharge processes of care (medication reconciliation) by dialysis facilities, and coordination of care with other providers in the pre and post-discharge periods (communication with the dialysis provider; medication reconciliation) have the potential to prevent hospital readmissions for ESRD dialysis patients. Preventing hospital readmissions is regarded as a shared responsibility that can be impacted by both dialysis providers and hospitals.

Several studies and commentaries strongly suggest pre- and post-discharge interventions within the purview of dialysis providers may reduce the risk of unplanned readmissions within the ESRD chronic dialysis population (Assimon, Wang, and Flythe 2018; Plantinga et al 2018; Flythe et al 2017, 2016; Chan et al 2017; Assimon and Flythe 2017; Plantinga and Jaar 2017). Plantinga et al (2018) found that interventions in the immediate post-discharge period were associated with reduced readmission risk among hemodialysis patients. They also suggest that post-discharge processes of care may help identify certain patients at higher risk for readmission, creating opportunities for dialysis providers to initiate interventions to reduce readmissions.

Chan and colleagues (2009) found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission. Assessments included hemoglobin testing and modification of EPO dose; mineral and bone disease testing and modification of vitamin D; and, importantly, modification of dry weight after discharge. The risk of unplanned hospital readmission was reduced when these assessments were completed within the first seven days post-hospital discharge. In a commentary (Wish 2014) the Chan 2009 study and several others are cited as examples of the potential for care coordination to reduce readmissions among ESRD dialysis patients. The findings from Chan 2009 are further supported by results from a recent study (Lin et. al. CJASN, 2019) comparing principal diagnosis of index hospitalizations and their associated readmissions. Tables included in the paper's supplementary materials clearly demonstrate that a significant portion of readmission principal discharge diagnoses are for dialysis-related conditions. For example, regardless of the index hospitalization cause (i.e. infectious, endocrine, cardiovascular, GI, dermatologic, renal, etc), the top principal discharge diagnosis lists for related readmissions prominently included diagnoses typically associated with fluid overload and failure of fluid management in dialysis patients (fluid overload, hypertension, CHF, etc). These results support the early findings from Chan 2009, nearly a decade earlier, showing that adjustment of patient target weight in the early post-hospitalization discharge period (to adjust for the frequent weight loss and/or in-hospital re-assignment of a lower post-dialysis target weight) is a likely mechanism for a substantial minority of unplanned readmissions in the US chronic dialysis population.

Finally, findings from the first two performance years of the Center for Medicare and Medicaid Innovation's Comprehensive ESRD Care Initiative suggest care coordination may reduce readmission risk (The Lewin Group, 2019). The findings of this controlled study showed an overall decrease in the percentage of Medicare beneficiaries with at least one readmission, among those aligned to an ESRD Seamless Care Organization, relative to a matched comparison group of facilities

Studies in the non-dialysis setting have cited post-interventions or a combination of pre-and post-discharge interventions as drivers for reducing unplanned readmissions (Dunn 1994; Bostrom 1996; Dudas 2001; Azevedo 2002; Coleman 2004; Coleman 2006; Balaban 2008; Braun 2009; Naylor 1994; McDonald 2001; Creason 2001; Ahmed 2004; Anderson 2005; Jack 2009; Koehler 2009; Parry 2009). However, a recent study and related commentary challenge the reported magnitude of reductions in hospital-wide readmissions since 2010, as part of the publicly reported Hospital Wide Readmission (HWR) measure for the Hospital Readmission Reduction Program (HRRP) (Wadhera, Yeh, and Joynt-Maddox 2019; Ody et al 2019). They suggest the potential driver of these reductions is in part attributed to a change in diagnosis coding policy for inpatient claims that took effect in October 2012. While it is not yet settled whether the reductions were primarily or only nominally driven by the ability of hospitals to report more condition diagnoses, resulting in more robust comorbidity risk adjustment in the measure, the concern has generated attention about whether reported improvements in readmission rates is a result of the HWR and by extension better care delivery by hospitals. These concerns are not considered germane to drivers of readmission reduction based on the dialysis facility readmission measure. The SRR was implemented by CMS in 2015, after the 2012 coding changes took effect. Therefore trends in dialysis patient 30-day readmissions only reflect the period since the claims based diagnoses coding changes, and observed reductions since that time are not considered an artifact of the 2012 inpatient diagnosis coding changes.

Ahmed A, Thornton P, Perry GJ, Allman RM, DeLong JF. Impact of atrial fibrillation on mortality and readmission in older adults hospitalized with heart failure. Eur J Heart Fail. 2004;6(4):421–426.

Anderson MA, Clarke MM, Helms LB, Foreman MD. Hospital readmission from home health care before and after prospective payment. J Nurs Scholarsh. 2005;37(1):73–79.

Azevedo A, Pimenta J, Dias P, Bettencourt P, Ferreira A, Cerqueira-Gomes M. Effect of a heart failure clinic on survival and hospital readmission in patients discharged from acute hospital care. Eur J Heart Fail. 2002 Jun;4(3):353–359.

Balaban RB, Weissman JS, Samuel PA, Woolhandler S. Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study. J Gen Intern Med. 2008;23(8):1228–1233.

Bostrom J, Caldwell J, McGuire K, Everson D. Telephone follow-up after discharge from the hospital: Does it make a difference? Appl Nurs Res. 1996;9:47–52.

Braun E, Baidusi A, Alroy G, Azzam ZS. Telephone follow-up improves patients satisfaction following hospital discharge. Eur J Internal Med. 2009;20:221–225.

Chan K, Lazarus M, Wingard R, et al. "Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge." Kidney International (2009) 76:331-41.

Coleman E, Parry C, Chalmers S, et al. The care transitions intervention. Arch Internal Med. 2006;166:1822–1828.

Creason H. Congestive heart failure telemanagement clinic. Lippencotts Case Management: Managing the Process of Patient Care. 2001 Jul-Aug;6(4):146-56.

Dudas V, Bookwalter T, Kerr KM et al. The impact of follow-up telephone calls to patients after hospitalization. American Journal of Medicine. 2001; 111(9B):26S-30S

Dunn JM, Elliot TB, Lavy JA et al. Outpatient clinic review after arterial reconstruction: is it necessary? Annals of the Royal College of Surgeons of England. 1994 Sep;76(5):304-6.

Jack B, Chetty V, Anthony D, et al. "A reengineered hospital discharge program to decrease rehospitalizaton." Annals of Internal Medicine (2009) 150:178-88.

Koehler BE, Richter KM, Youngblood L et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. Journal of Hospital Medicine. 2009 Apr;4(4):211-8.

McDonald, MD. The hospitalist movement: wise or wishful thinking? Nurse management. 2001 Mar;32(3):30-1.

Naylor M, Brooten D, Jones R et al. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Annals of Internal Medicine. 1994 Jun 15;120(12):999-1006.

Parry C, Min SH, Chugh A et al. Further application of the care transitions intervention: results of a randomized controlled trial conducted in a fee-for-service setting. Home Health Care Services Quarterly. 2009;28(2-3):84-99.

United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

Numerator Statement: Each facility's observed number of hospital discharges that are followed by an unplanned hospital readmission within 4-30 days of discharge.

Denominator Statement: The denominator for a given facility is the expected number of the observed index hospital discharges that result in an unplanned readmission in days 4-30 and that are not preceded by an unplanned or competing event. The expectation accounts for patient-level characteristics, including measures of patient comorbidities, and the discharging hospital, and is based on estimated readmission rates for an overall population norm that corresponds to an "average" facility.

Denominator Exclusions: Index Discharge Exclusions:

A live inpatient hospital discharge is excluded if any of the following hold:

- Associated with a stay of 365 days or longer
- It is against medical advice
- It Includes a primary diagnosis of cancer, mental health or rehabilitation
- It Includes revenue center codes indicating rehabilitation

- It occurs after a patient's 12th hospital discharge in the calendar year
- It is from a PPS-exempt cancer hospital

• It is followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit) or any other competing event (see S.5)

Measure Type: Outcome

Data Source: Claims, Registry Data

Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Dec 23, 2014 Most Recent Endorsement Date: Dec 09, 2016

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

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

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

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

Criteria 1: Importance to Measure and Report

1a. Evidence

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence \cup since the prior evaluation.

<u>1a. Evidence.</u> The evidence requirements for a health outcome measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

Summary of prior review in 2015:

- The developer cites several studies in non-ESRD populations that demonstrated the impact of pre- and post-discharge interventions to reduce admission and unplanned readmission rates.
- The developer cites one study in the ESRD population in which certain post-discharge assessments and changes in treatment (e.g., Hb testing and modification of EPO dose; mineral and bone density testing and modification of vitamin D; modification of dry weight after discharge) at the dialysis facility may be associated with a reduced risk of readmission.
- In 2015, the Committee agreed that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmissions. One committee member was

concerned that the cause of the reduced risk of admissions had more to do with interventions by nephrologists, rather than the dialysis unit.

Changes to evidence from last review

□ The developer attests that there have been no changes in the evidence since the measure was last evaluated.

☑ The developer provided updated evidence for this measure:

Updates:

• The developer cites several studies in ESRD chronic dialysis populations that demonstrated the impact of pre and post-discharge interventions to reduce admission and unplanned readmission rates. The developer also cites several articles referencing dialysis facility-level process of care interventions – namely Hb testing and modification of EPO dose; mineral and bone density testing and modification of vitamin D; and modification of dry weight after discharge – and structures of care – specifically, nurses-to-toal staff ratios. The developer further cites findings from the first 2-years of the CMMI Comprehensive ESRD Care Inititiave, suggesting that Medicare patients within an ESRD Seamless Care Organization have an overall decrease in readmissions compared to a matched comparator group of dialysis facilities.

Question for the Committee:

• Is there at least one intervention that the provider can undertake to achieve a change in the measure results?

Guidance from the Evidence Algorithm

Box 1: The measure assesses a healthcare outcome \rightarrow Box 2: The developer has provided empirical data that there is a relationship between the measured outcome and at least one healthcare outcome \rightarrow Yes (PASS)

Preliminary rating for evidence: 🛛 Pass 🗆 No Pass

1b. Gap in Care/Opportunity for Improvement and Disparities

Maintenance measures - increased emphasis on gap and variation

<u>1b. Performance Gap.</u> The performance gap requirements include demonstrating quality problems and opportunity for improvement.

- The developer provides performance data from 2016 2018 and interquartile range (IQR) of 0.33 for 2016 and 2017 and 0.34 for 2018:
 - 2016: 6,442 facilities, SRR mean: 0.99, SD: 0.28, min: 0.00, max: 2.61, IQR: 0.33, deciles (10-90): 0.65, 0.78, 0.87, 0.93, 1.00, 1.06, 1.13, 1.20, 1.32
 - 2017: 6,682 facilities, SRR mean: 1.00, SD: 0.28, min: 0.00, max: 2.47, IQR: 0.33, deciles (10-90): 0.66, 0.79, 0.84, 0.94, 1.00, 1.06, 1.13, 1.21, 1.32
 - 2018: 6,937 facilities, SRR mean: 1.00, SD: 0.29, min: 0.00, max: 3.69, IQR: 0.34, deciles (10-90):
 0.66, 0.78, 0.87, 0.94, 1.00, 1.06, 1.13, 1.21, 1.34

Disparities

• The developer examined potential disparities affecting patients based on, gender, race, ethnicity, dual eligible status, and the Area Deprivation Idex across three years (2016 – 2018). In the most recent year of data (2018), the measure identified differences in gender, race, and dual-eligibility.

Questions for the Committee:

• Is there a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement: 🛛 High 🛛 Moderate 🖓 Low 🖓 Insufficient

Committee Pre-evaluation Comments:

Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures – are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- There is now increased number of reports and data from a CMMI model that supports this measure.
- Pass
- The evidence appears to be directly related to the outcome being measured.
- No concerns
- measure for maintenance/re-endorsement. Still evidence re potential to reduce readmission rates.
- somethat

• The developer cites studies in ESRD chronic dialysis populations that demonstrated the impact of pre and post discharge interventions to reduce admission and unplanned readmission rates. Also articles reference dialysis facility level process of care interventions. Findings from the first 2 years of the CMMI Comprehensive ESRD care initiative...suggest that Medicare patients within an ESRD Seamless Care organization have an overall decrease in readmission compared to a matched compared group of dialysis facilities. Overall acceptable.

• Yes, evidence in favor of this measure is shown

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

• Performance data on the measure is provided. Supports disparities which could be addressed either by a performance measure or improvements in the risk adjustment modeling.

• differences in gender, age and dual eligibile

• Performance data was provided and demonstrates opportunities to improve care across subgroups of patients.

- No concerns
- gap exists. 2018: 0.66-1.34, comment on differences related to gender/race/dual elig
- unclear
- in 2018, the measure identified differences in gender, race, and dual-eligibility
- Yes, I think so

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

- 2b. Validity: Testing; Exclusions; Risk-Adjustment; Meaningful Differences; Comparability; Missing Data
- 2c. For composite measures: empirical analysis support composite approach

Reliability

<u>2a1. Specifications</u> requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

<u>2a2. Reliability testing</u> demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

<u>2b2. Validity testing</u> should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

<u>2d. Empirical analysis to support composite construction</u>. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Measure evaluated by Technical Expert Panel (TEP)? ☑ Yes □ No

Evaluators:

- Franklin Maddux, MD, FACP,
- Andrew Narva, MD, FACP, FASN
- Michael Fischer, MD, MSPH
- Lori Hartwell

Renal TEP Review (Combined)

Renal TEP Summary:

This measure was reviewed by an NQF-convened Renal TEP. The summary is provided below. The developer also provided responses to the concerns raised by the Renal TEP, which can be found on the <u>Standing</u> <u>Committee SharePoint site</u>.

- Measure Evidence
 - Several TEP members stated that the evidence demonstrates that interventions can be performed by dialysis facilities to impact hospitalizations.
 - There was concern regarding attribution to dialysis facilities as not all readmissions are due to to dialysis care, but can be due to poor discharge planning.
- Measure Specifications

- Several TEP members commented that the population is clinically appropriate and congruent with the measure intent.
- There were questions on how a hospitalization defined, specifically how ED observation stays are handled. The developer clarified that ED observation stays are included in a separate performance measure.
- Additionally, one TEP member mentioned that the measure is complex in terms of definitions and codes. This complexity may make it difficult for dialysis facilities to understand which patients are they are accountable for prospectively, ultimately making it difficult to impact quality outcomes for this population.

• Measure Exclusions

- \circ $\;$ There were comments that the exclusions are appropriate and relevant.
- One TEP member shared that the measure should exclude hospitalizations that are not dialysis-related, reiterating the concern that the measure captures all-cause readmissions.

• Validity Testing

- There was concern for switching from all Medicare claims to inpatient claims and concern that the measure is not valid or reliable if it doesn't exclude things that are unrelated to a dialysis care.
- Some members felt that correlations are appropriate and consistent with dialysis care, but that the correlations are small.

• Risk adjustment

• Generally the TEP was supportive of the risk adjustment model, however, several members expressed concern with the lack of SDS adjustment and the inclusion of all cause readmissions.

Complex measure evaluated by Scientific Methods Panel? \boxtimes Yes \square No

Evaluators:

- Bijan Borah, MSc, PhD
- Jack Needleman, PhD
- Jennifer Perloff, PhD
- Zhenqiu Lin, PhD
- Jeffrey Geppert, EdM, JD
- Eugene Nuccio, PhD
- Christie Teigland, PhD
- Susan White, PhD, RHIA, CHDA
- Ronald Walters, MD, MBA, MHA, MS

Methods Panel Review (Combined)

Scientific Acceptability: Preliminary Analysis Form

- Reliability: H-0; M-4; L-3; I-0 (Consensus not reached)
- Validity: H-0; M-3; L-5; I-0 (Not Pass)

Methods Panel Evaluation Summary:

- In their preliminary analyses, subgroup reviewers did not pass this measure on validity and consensus was not reached on reliability. Reviewers raised concerns with the reliability testing score, which was considered modest/low.
- Given the similar methodology used in testing score-level reliability between this measure and others from the same developer reviewed this cycle, the panel ultimately determined that consensus could not be reached.

- The SMP concluded that the final vote on reliability should lie with the Standing Committee by evaluating all of the measures with similar methodologies together and determine the adequacy of the reliability results across all similar measures.
- For validity, the concerns centered on the adequacy of the correlations presented for measure score validity testing. The developers provided a detailed response to the panel's concerns. However, reviewers still found the results did not adequately demonstrate measure score validity and did not pass the measure on validity. This aspect of measure testing is eligible for futher consideration by the Standing Committee in relationship to other measures submitted for review.
- Specifications:
 - No issues
- Reliability Testing Performance Score Reliability
 - For maintenance measures, summarize the reliability testing from the prior review:
 - The developer estimated the inter-unit reliability (IUR) using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by an one-way analysis of variance (ANOVA).
 - \circ Using 2009 data, the IUR = 0.55 (F statistic = 2.24).
 - Describe any updates to testing:
 - There were n=6,937 (with an average of 55.1 patient-years-at-risk) Medicare-certified dialysis facilities with at least 11 eligible index discharges in 2018 included in the testing and analysis*.
 - In previous submission, facility size was measured by the number of distinct patients treated by the facility during the year of interest. For the 2019 submission, facility size is measured by patient-years-at-risk in 2018.

• Method(s) of reliability testing:

- \circ The developer calculated the both an inter-unit reliability (IUR) and an additional metric of reliability, termed the profile IUR (PIUR).
- \circ The PIUR is based on the measure's ability to consistently flag the same facilities.
- This empirical reflagging rate is calibrated to give the PIUR by determining the IUR value that would yield this reflagging rate in the absence of outliers.
- The PIUR measures reliability in terms of the probability of reflagging rates but is on the same scale as IUR (0 to 1). The higher PIUR compared to the IUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself.
- The PIUR is substantially larger than the IUR when the data include many outliers or extreme values that are not captured in the IUR itself.

• Reliability testing results:

- The overall IUR performance is 0.35, indicating that 35% of the variation in the SRR can be attributed to the between-facility differences and the remaining within facility variation. The overall PIUR was 0.61.
- The value obtained for the IUR is moderate in size. The PIUR is larger and demonstrates that the SRR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.
- Validity- Performance Score Validity (Empirical)
 - For maintenance measures, summarize the validity testing from the prior review:

- Validity of the SRR was assessed through correlations of this measure with other quality measures in use, and in May 2012, presented a preliminary version of the SRR to a CMS Technical Expert Panel (TEP) for clinical face validity.
- The developer used Pearson correlation coefficients to examine the relationship between the SRR and other facility-level practice pattern.
- Describe any updates to testing:
- $_{\odot}$ Empirical validity testing of the measure score updated with 2018 data and face validity was conducted with a TEP in 2012

• Method(s) of validity testing:

- \circ The developer assessed the validity of the measure by examining the correlation of this measure with other quality measures in use, using Spearman correlations.
- \circ The developer hypothesized negative association between SRR and vascular access: standardized fistula rate.
- The developer hypothesized positive relationships between SRR and SHR (standardized hospitalization rate), vascular access: long term catheter rate (>= 3 continuous months), and SMR (mortality rate).
- $_{\odot}$ In 2012, a TEP was held specifically to consider the clinical face validity of the measure
- Validity testing results:
 - \circ The measure is positively correlated with the one-year Standardized Hospitalization Ratio for Admissions (SHR) (r = 0.39, p < 0.0001), the Standardized Mortality Ratio (SMR) (r = 0.10, p < 0.0001), and long-term catheter use (r = 0.04, p = 0.0006). The SRR is negatively correlated with the rate of patients using a fistula (r = -0.06, p < 0.0001). The hypothesized relationships were confirmed by empirical testing.
 - Hospitalization as measured by SRR has the expected correlations with outcomes and processes of care commonly thought to be related to quality of care.
 - Higher SRR was associated with higher SHR rates, facility mortality rates (SMR) and higher long-term catheter rates.
 - The developer found higher values of SRR were also associated with lower AV Fistula rates (SFR).
 - The developer also maintains the measure on the basis of face validity based on the 2012 TEP; however, the measure more information is needed to determine if there was a systematic evaluation of face validity of the measure score.
- Exclusions:
 - The developer excludes planned readmissions from the numerator and the following hospital discharges from the denominator using the below criteria:
 - Associated with a stay of 365 days or longer (n=54, 0.01%)
 - Are against medical advice (n=13,391, 1.9%)
 - Include a primary diagnosis of cancer, mental health or rehabilitation or a revenue center code indicating rehabilitation (n=10,051, 1.4%)
 - $_{\odot}$ Occur after a patient's 12th hospital discharge in the calendar year (n=5,975, 0.9%)
 - Are from a PPS-exempt cancer hospital (n=964, 0.1%)
 - Are followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit), or any other competing event* (n=85,831, 12.2%) (e.g., admissions to rehabilitation or psychiatric hospitals, death, transplant, loss to follow up, withdrawal or recovery)

• Risk adjustment Summary:

- \circ Area under the receiver operating characteristic (ROC) curve (the c-statistic) = 0.6768 \circ The developer uses a three-stage model:
 - first of which is a fixed-effects logistic regression model
 - second of which is a double random-effects logistic regression model
 - third of which is a mixed-effects logistic regression model
- The adjustment is made for patient age, sex, diabetes, duration of ESRD, Medicare Advantage status at discharge, nursing home history in past year, BMI at incidence, prioryear comorbidities, length of hospital stay and presence of a high-risk diagnosis at discharge.
- The list of 53 past-year comorbidity variables are selected from 233 indicators of AHRQ CCS diagnosis categories with prevalence greater than 0.1% using a score-test based sample splitting forward selection approach.
- The developer noted that due to the nominal differences in flagging when adjusting for SDS/SES, coupled with the risk of reducing patients' access to high quality care supports the decision to not adjust SRR for the selected SDS/SES factors.

Questions for the Committee regarding reliability:

- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- Do the IUR values demonstrate sufficient reliability of this measure?
- Is the PIUR method appropriate for demonstrating reliability for this measure?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- Is this 3-stage risk adjustment modeling approach appropriate?
- Do you agree with the developer's decision, based on their analysis, to not include SES factors (race, ethnicity and patient level factors) in their risk-adjustment model?
- Does this measure identify meaningful differences about quality?

Preliminary rating for reliability: High Moderate Low Insufficient

Specifications precise unambiguous and complete (Box 1) \rightarrow Empirical reliability testing conducted (Box 2) \rightarrow Testing conducted at computed measure score level (Box 4) \rightarrow Method described and appropriate (Box 5) \rightarrow Level of certainty or confidence that measure scores are reliable (Box 6) \rightarrow MODERATE (rationale that reliability improves as the sample sizes increase, medium and small facilities have lower reliability estimates)

Preliminary rating for validity: □ High ⊠ Moderate □ Low □ Insufficient

Specifications consistent with evidence (Box 1) \rightarrow Potential threats to validity assessed (Box 2) \rightarrow Empirical validity testing of measure as specified (Box 3) \rightarrow Testing performed with measure score (Box 6) \rightarrow Method described and appropriate (Box 7) \rightarrow Level of certainty or confidence that measure score is a valid indicator of quality (Box 8) \rightarrow Moderate

Committee Pre-evaluation Comments:

Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- No concerns.
- None
- The data elements and algorithm appear to be clearly defined.
- No concerns

• as with other measures, attribution to the dialysis unit may be in appropriate depending on the reason for the hospitalization. Agree with other reviewers that specs re: exclusions are complex

• attribution and dc disposition and factor

• The overall IUR performance is 0.35, indicating that 35% of the variation in the SRR can be attributed to the between-facility differences and the remaining within facility variation. The overall PIUR was 0.61. value obtained for the IUR is moderate in size

• yes

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- Concern about the IUR and PIUR . Is this measure only reliable at the extremes?
- none
- None.
- No concerns
- TEP had concerns re: IUR drop and whether PIUR is able to measure outliers
- yes strenght of correlations
- No concerns
- No

2b1. Validity -Testing: Do you have any concerns with the testing results?

- Both TEPs questioned the validity almost uniformly.
- none
- None.
- No concerns

• validity supported by correlation (in appropriate directions) with other measure of higher quality dialysis care, e.g. presence of AV fistula

same

• This is the only message that includes pediatric patients. Curious what the rationale is for this inclusion compared to other measures that exclude patients under 18 years of age. Inclusion of pediatric patients makes this measure less comparable to other hospital readmission measures such as the HWRR and other criterion specific readmission rates

• No

2b4-7. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data)2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

• Questions remain about the exclusion of MA patients and also readmissions for non-dialysis events. Can the measure identify meaningful differences in performance?

• no

• Missing data may constitute a threat to the validity of this measure.

No concerns

• Correlates to SHR and SMR. Relatively few facilities were "worse than expected", ?the ability to find meaningful differences.

- attrivution
- No concerns
- 2b6

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment)2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure?2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- Should SES adjustment be retained in the risk adjustment?
- yes

• According to the developer response, social risk factors were not included as risk adjustment variables.

No concerns

• did include zip codes, dual eligibility, race, gender in testing, but ultimately removed most SDS factors from final adjustment.

- SES
- No issues

Criterion 3. Feasibility

Maintenance measures - no change in emphasis - implementation issues may be more prominent

<u>3. Feasibility</u> is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

- The developer states that all data elements are in defined fields in electronic claims. Data collection is accomplished via Medicare Claims and CROWNWeb, a web-based and electronic batch submission platform maintained and operated by CMS contractors.
- Measures reported on Dialysis Facility Compare are reviewed on a regular basis by dialysis facility
 providers. The developer noted that the comments and questions received in the past 3 years for SRR
 showed only rare instances of concern regarding inaccurate or missing data.

Questions for the Committee:

- Are the required data elements routinely generated and used during care delivery?
- Are the required data elements available in electronic form, e.g., EHR or other electronic sources?

Preliminary rating for feasibility:	: 🛛 High	Moderate	🗆 Low	Insufficient
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Committee Pre-evaluation Comments: Criteria 3: Feasibility

3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?

- No concerns.
- yes
- No current concerns about the data collection strategy.
- No concerns
- already in use, electronic claims data. No concerns
- none
- Data collection is accomplished via Medicare Claims and CROWNWeb
- EHR implementation might be difficult

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

<u>4a. Use</u> evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure		
Publicly reported?	🛛 Yes 🛛	Νο
Current use in an accountability program?	🛛 Yes 🛛	No 🗌 UNCLEAR
OR		
Planned use in an accountability program?	🗆 Yes 🛛	No

Accountability program details:

- The measure is currently used in Dialysis Facility Compare (DFC):
 - DFC provides detailed information about Medicare-certified dialysis facilities. Beneficiaries can compare the services and the quality of care that facilities provide.
 - Accountable entities include All Medicare-certified dialysis facilities in the U.S. that are eligible for the measure, and have at least 10 patient years at risk (due to public reporting requirements). For the most recent update to DFC (January 2020), 7,578 facilities had data reported on DFC.
- Patients included: All patients who meet the requirements to be included in the measure from included facilities.
- This measure is used in the End-Stage Renal Disease Quality Incentive Program (QIP):
 - The ESRD QIP will reduce payments to ESRD facilities in the Un.S. that do not meet or exceed certain performance standards. The measure was added to the program for PY2017.
 - Accountable entities include all Medicare-certified dialysis facilities that are eligible for the measure, and have at least 10 patient years at risk (due to public reporting requirements). For the most recent QIP report that is publically available (PY 2020), this was 7,420 facilities.

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others:

- The developer states that measure results are currently reported on DFC and in the ESRD QIP.
- For DFC, feedback can be provided any time through contacting the dialysisdata.org helpdesk. The developer states that the comments received are mainly technical in nature, asking for clarification on how the SRR is calculated for particular facilities, including questions about patient assignment and application of exclusion criteria.
- For the ESRD QIP, feedback can be provided any time through contacting the QIP helpdesk. The developer stated that comments that were raised related to concerns with risk adjustment for SDS factors or clinical factors, attributabution to the dialysis faciliticies, and the measure's reliability, based on the measure's calculated IUR.

Additional Feedback:

• Comments were related to the use in the QIP were concerning risk adjustment, attribution, and measure reliability

Questions for the Committee:

- How have (or can) the performance results be used to further the goal of high-quality, efficient healthcare?
- How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: 🛛 Pass 🛛 No Pass

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

<u>4b. Usability</u> evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The measure developer states that there has been little to no improvement in the unadjusted and riskadjusted rates over the calendar years 2016 – 2018.
- Unadjusted (raw) Readmission Rates:
 - o **2016: 0.265**
 - o **2017: 0.264**
 - o **2018: 0.263**

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving highquality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

• The measure developer states that there are no unexpected findings

Potential harms

• The measure developer does not provide any information on potential harms

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use:
High Moderate Low Insufficient

Committee Pre-evaluation Comments: Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided?4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Measures are reported on DFC and used in ESRD QIP. There is a mechanism for user feedback.
- publicly reported
- It appears that feedback has been considered when weighing changes to the measure.
- No concerns

• currently in use on ESRD QIP, attribution to the dialysis facilit has been a concern, also report that reliability based on IUR has been a concern (p. 96)

- currently in use
- no further feedback
- 4a2 Yes

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations?4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- No information provided on benefits and harms.
- yes
- Yes, the performance results can be used to further the goal of high-quality, efficient healthcare.
- No concerns
- hasn't been much definite improvement over time. no harms reported
- needs discusison
- No unexpected findings
- 4b2. In general benefits outweight harms

Criterion 5: Related and Competing Measures

Related or competing measures

- 0369 : Standardized Mortality Ratio for Dialysis Facilities
- 1463 : Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
- 1789 : Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)
- 2510 : Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)

Harmonization

- The measure developer notes that the SRR is harmonized with the Standardized Hospitalization Ratio for Admissions (NQF #1463) and Standardized Mortality Ratio (NQF #0369).
- The developer notes that SRR, SHR, and SMR all restrict to inpatient claims for comorbidity risk adjustment. However, SRR adjusts for a different set of comorbidities that are associated with a high risk of readmission.
- The developer notes that SRR is harmonized with both the HWR and SNFRM measures in restricting to the use of inpatient Medicare claims for comorbidity risk adjustment, and exclusion of planned readmissions. The developer notes several differences, however, with the inclusion/exclusion criteria and the risk adjustment of SRR compared to HWR and SNFRM

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- yes. the measure is harmonized.
- I am not aware of any competing measures.
- No concerns
- multiple related measures, harmonized to SHR 1463
- readmissions all cause
- Not Sure

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: June 12, 2020

• There have been no public comments or support/non-support choices as of this date.

Renal Technical Expert Panel Combined Input

Measure Number: 2496

Measure Title: Standardized Readmission Ratio (SRR) for Dialysis Facilities

1. Measure Evidence (Sections 1a. in submission form – see Evidence attachment)

1a. To what extent does the evidence provided in the submission form support the relationship of the readmission outcome to clinical processes or structures of care in dialysis facilities?

TEP Member #1: My big concern is attribution. How are these readmissions tied to care provided by the dialysis facility? They reflect hospital care and discharge planning as well as dialysis facility care. Restrict to dialysis-related complications may help but not resolve the problem. They mention CMI and ESCOs – sure, but not all dialysis facilities are in ESCOs. The fact that there is no demonstrated improvement in performance makes this concern even greater – facilities do not have influence over it.

TEP Member #2: Not all causes of readmission are due to dialysis care.

TEP Member #3: There is clear evidence that certain patient discharges to home from an acute care setting can be enhanced by certain dialysis facility interventions if those interventions are able to be provided before the readmission. Many readmissions are in fact due to poor discharge choices that result in ultra-rapid readmission before the dialysis facility has the chance to intervene. Further, certain "next sites of care" if not a patient's home should clearly be considered circumstances in which the readmission may not relate to actions that can be deployed in a dialysis facility. So, the circumstances of the patients' discharge will likely have an impact on the likelihood of a readmission.

TEP Member #4: The evidence is strong that readmission is an indicator of the dialysis care process. It is not unusual for dialysis providers to suggest that, because they are not responsible for all aspects of a patient's care, they should not be held accountable by measures such as this. However, dialysis patients receive care that is often fragmented and the failure to collect information such as this would not be in their interests. Preliminary data from the ESCO is consistent with the validity and importance of this measure.

2. Measure Specifications (Sections S.4 – S.7 in submission form)

2a. To what extent is the measure population clinically appropriate?

TEP Member #3: The population is basically appropriate, but the definition of what is a planned hospitalization creates difficulty in classifying patients who will populate the numerator and denominator in the measurement.

TEP Member #4: It is appropriate.

2b. To what extent are the definitions and codes used to identify the measure population clinically consistent with the intent of the measure?

TEP Member #1: How are observation stays treated? Does the hospitalization have to be > 24 hrs?

TEP Member #2: It's appropriate to know the hospitalization. The measure has some issues of not distinguishing what is dialysis related.

TEP Member #3: The complexity of the various choices for inclusion and exclusion in the numerator and denominators makes the SRR almost impossible for an individual clinic to understand who they are measured on prospectively and what can be done generally in the facility to impact just these patients that get included in the measure. Many of these measures fail to account for a dialysis facility trying to respond to attain certain measure goals. I think the definitions and codes to this measure are difficult for facilities to fully understand given the puts and takes required to get to the calculations. They are not in a position to model their performance and the impact of various interventions, so the meaningfulness of the measure is diminished as a result of this complexity.

TEP Member #4: They are congruent.

3. Measure Exclusions (Sections S.8 – S.9 in submission form and 2b2.1 – 2b2.3 of Testing attachment)

3a. To what extent are exclusions identified and clinically relevant for the measure intent?

TEP Member #3: The exclusions all make sense and are relevant. The open question is what additional exclusions represent features that are amenable to facility impact from interventions that would be applied to reduce readmissions.

TEP Member #4: They are well identified and relevant.

3b. To what extent are the exclusions, if any, consistent with the evidence?

TEP Member #3: The known exclusions have an evidence base for their inclusion.

TEP Member #4: They are mostly self-evident.

3c. To what extent do the exclusions, if any, represent a large proportion of patients that could bias the measured population?

TEP Member #1: Why are Medicare Advantage patients not excluded?

TEP Member #2: The measure needs to exclude readmission hospitalizations that are not dialysis related.

TEP Member #3: The measure itself carries a wide amount of bias from the complexity of the definitions, the expected rate calculations and both the inclusions and exclusions. It is a complex and difficult measure to unpack for the non-statistician. I would suggest that all elements of the definition of the SRR invoke bias in the result that reduces the ability of the measure to be directly actionable by the facility being measured despite the fact that certain interventions are known in many hands to impact beneficially the high rate of readmissions in patients requiring renal replacement therapy.

TEP Member #4: Exclusions are appropriate.

4. Validity Testing (Sections 2b.1.2 – 2b.1.4 of Testing attachment)

4a. To what extent are the magnitudes and directions of the correlations with other measures what you would expect?

TEP Member #1: Switching from all Medicare claims to just inpatient claims should be examined for its effect on performance – see concerns below

2. The r correlation values are very small

TEP Member #2: The measure is not valid or reliable if it doesn't exclude things that are unrelated to a dialysis care.

TEP Member #3: The correlations are small in my opinion and in directions that would be expected. Combined with the reliability IUR testing being poor this is a difficult measure to feel fully confident about in being representative of how a clinic can address the problem identified in readmission rates being high. I do not find comfort in the Validity or the Reliability of this measure.

TEP Member #4: The correlations with other measures (fistula rate, SMR, SHR) are consistent with our understanding of dialysis processes of care. The SRR is particularly useful when this measure is viewed as complementary to the SHR.

5. Risk Adjustment (Sections 2b.3 of Testing attachment)

5a. To what extent are the covariates (factors) included in the risk-adjustment model clinically relevant and consistent with the measure's intent?

TEP Member #1: I am concerned about use of inpatient claims for comorbidity adjustment. This likely leads to incomplete data capture. Moreover, you are only capturing comorbidities on patients hospitalized. What about the patients at a dialysis facility that are not hospitalized? You have no comorbidity data on them so this compromises the expected calculation for a facility.

SDS factors should be included. They change the status of about 6% facilities, which is a big deal for those facilities. Also, as the literature suggests, these factors are NOT under the control of the dialysis facility and have impacts on hospitalizations that have nothing to do with the dialysis facility.

TEP Member #3: The intensive risk adjustment is not only needed but is a result of the complexity of trying to address the faults of such a complex measure. Surely, there is an argument that the risk adjustment covariates have a basis that is clinically relevant, but the scale and scope of these adjusters and the three level adjustment is a sign that there is a problem at the core of the measure that there are too many factors that impact readmissions that are not relevant to a dialysis facility. I find the logic of the risk adjustment a sign of a weakness of the measure including that fact that the nature of the measure as a ratio presumes that there is truly a local result that is really comparable to a expected that doesn't include race and geography. Admission to a hospital and readmission included have many local practice pattern influences for which there are reasons that local health systems operate the way that they do. The effects of local expertise and access to care

options are not uniform in our country. In the midst of our current COVID-19 pandemic the population disruption will wreak havoc on a measure like this one as the index hospitalizations due to pandemic would never have been expected in the risk adjustment. This current state is an example of where a measure like this quickly falls apart and will be unlikely to correct quickly.

TEP Member #4: They are clinically relevant and well explained in the response of the measure developer to the SMP analysis. However, I am not an expert in risk adjustment analysis.

Combined Methods Panel Scientific Acceptability Evaluation
Measure Number: 2496
Measure Title: Standardized Readmission Ratio (SRR) for Dialysis Facilities
Type of measure:
Process Process: Appropriate Use Structure Efficiency Cost/Resource Use
🛛 Outcome 🛛 Outcome: PRO-PM 🛛 Outcome: Intermediate Clinical Outcome 🗌 Composite
Data Source:
🖾 Claims 🛛 Electronic Health Data 🔹 Electronic Health Records 🖓 Management Data
🗆 Assessment Data 🛛 Paper Medical Records 🛛 Instrument-Based Data 🛛 Registry Data
Enrollment Data Other
Level of Analysis:
🗆 Clinician: Group/Practice 🛛 Clinician: Individual 🛛 🖾 Facility 🔲 Health Plan
Population: Community, County or City Population: Regional and State
Integrated Delivery System Other
Measure is:

□ **New** ⊠ **Previously endorsed (**NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented?
Yes
No

Submission document: "MIF_xxxx" document, items S.1-S.22

NOTE: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.

2. Briefly summarize any concerns about the measure specifications.

Panel Member #2 Concern that baseline comorbidities are based on discharge claim only (due to lack of available prior year claims data for Medicare Advantage enrollees). The discharge claim typically includes only a subset of relevant dx and would not reflect a comprehensive risk profile (i.e., patient may have other documented dx that are not recorded on discharge claim that would increase risk level and affect expected readmissions).

Panel Member #3

a.) I like that the performance period is 4-30 days to remove clearly unstable patients who have been inappropriately discharaged from the acute care hospital.

- b.) Virtually all of the references cited to justify the measure are more than 10 years old. Why were these not updated for this submission?
- c.) Based on MIF S.4 statement: Why is the numerator based on "observed number of hospital discharges [treated by the dialysis unit]" and the denominator is "expected number of the observed index hospital discharges [treated by the dialysis unit]"? These are likely to be different numbers.
 Based on MIF S.5 statement, the numerator is "the total number of index hospital discharges that are followed by unplanned readmissions within 4-30 days of discharge and that are not preceded by a "planned" readmission or other competing event that also occurred within 4-30 days of discharge". Why the discrepancy in the S.4 and S.5 statements?
- d.) Updated version of methodology (S.3.2 in MIF) changes the clinical categorization from HCC (MA payment-related) to AHRQ Clinical Classification System (CCS)—more clinically-based groupings; and restricts claims data to Medicare FFS patients—eliminating Medicare Advantage patients for whom there are no data.

Panel Member #7 The index discharge denominator exclusions are an interesting mixed bag. Since the original measure was proposed, a switch to only Medicare inpatient claims has been implemented due to the growing outpatient Medicare Advantage population and the loss of data regarding outpatient comorbidities. Changes have also been applied to identification of rehabilitation inpatient stays, and certain index discharges have been removed. The impact of longer stays in nursing homes has alos been clearly delinieated, up to 365 days from index discharge.

Panel Member #9 No specific concern.

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

- 3. Reliability testing level 🛛 🖾 Measure score 🖓 Data element 🖓 Neither
- 4. Reliability testing was conducted with the data source and level of analysis indicated for this measure □ ☑ Yes □ No
- 5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical** <u>VALIDITY</u> testing of <u>patient-level data</u> conducted?

□ Yes □ No Not Appliable—X (Panel Member #3)

6. Assess the method(s) used for reliability testing

Submission document: Testing attachment, section 2a2.2

Panel Member #2 The inter-unit reliability (IUR), which measures the proportion of measure variability that is attributable to the between-facility variation, was estimated using bootstrap sampling with replacement. They also calculated an additional reliability metric, the profile IUR (PIUR) to account for small between facility variation.

Panel Member #3 Bootstrap methodology used as some dialysis facilities had only relatively small numbers of discharged patients (# of patients => 11). Generated 100 random samples (with replacement.) from each facility.

Panel Member #7 Reasons are provided as to why ANOVA may not be applicable for between- and within facility variation for this standardized risk ratio. Instead, the inter-unit reliability is estimated. using a bootstrap approach with a resampling scheme. The analytics also uses a profile inter-unit reliability to consistently flag the identical facilities. A split-sampling is then utilized to test whether the same facilities can be identified as outliers in both subgroups.

Panel Member #8 Bootstrap technique – added profile IUR.

Panel Member #9 The developer calculated inter-unit reliability (IUR) for measure score reliability.

7. Assess the results of reliability testing

Submission document: Testing attachment, section 2a2.3

Panel Member #1 The IUR based on updated data has dropped significantly from 0.55 to 0.35. It would have been helpful to if the measure developer provide some justification for such substantial drop. While the measure developer contends that the larger PIUR (0.61) will be effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities, it would have been informative to see how much incremental number of outlier facilities that are identified by PIUR versus IUR.

Panel Member #2 They report an IUR = 0.35 and PIUR = 0.61. The higher PIUR compared to the IUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR. If there are no outliers, one should expect the PIUR to be similar to the IUR; but in cases where there are outlier providers, even measures with a low IUR can have relatively high PIUR and can be useful for identifying extreme providers, The PIUR score of .61 indicates moderate ability to detect outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.

Panel Member #3 The authors described an "inter-unit reliability (IUR)" and a "probabilistic IUR (PIUR)" approach to reliability—essentially a variation of ANOVA comparing variability between units. The results were modest to poor ("Overall, we found that IUR = .55 (F statistic = 2.24), which indicates that about one half of the variation in the SRR can be attributed to the between-facility differences and about half to within-facility variation.")

Panel Member #7 The IUR was 0.55 overall with a range of 0.46 to 0.61 for small to large facilities on the analysis from 2009. Fro the resubmission, the IUR was 0.35 and the PIUR was 0.61. It is stated that this correctly indicates the presence of outliers or heavier tails which is not capture in the IUR itself and therefore useful for identifying extreme outliers.

Panel Member #8 Table 1 is not updated with the new statistics broken down by facility size. No explanation of the decrease in IUR from original submission (0.55) to updated submission (0.35). This seems like a very large drop; it appears the submitter is attempting to rely on PIUR as a 'better' assessment of reliability. Unclear if PIUR is really a better measure or a replacement for IUR because of the drop. It would be helpful to see the PIUR for the previous submission to do an apples-to-apples comparison. The statistics submitted lead to the conclusion that the reliability is now lower than in the original submission.

Panel Member #9 IUR ranges from 0.46 for small facility to 0.61 for large facility. The results indicate moderate reliability of this measure.

8. Was the method described and appropriate for assessing the proportion of variability due to real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate.

Submission document: Testing attachment, section 2a2.2

 $\Box \boxtimes \mathbf{Yes}$

 $\boxtimes \Box$ No

□ Not applicable (score-level testing was not performed)

Panel Member #1 As indicated in 8 above, I would like to see more contrasting findings between the applications of IUR versus PIUR with regard to the testing dataset, which would have helped the discriminating power of PIUR over IUR as the measure developer claims.

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

Submission document: Testing attachment, section 2a2.2

 $\Box \boxtimes \mathbf{Yes}$

🗆 No

⊠ □ Not applicable (data element testing was not performed) Panel Member #2 NOTE: they do not appear to have performed data element reliaibility testing though their testing form indicates they did so.

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications and <u>all</u> testing results):

□ **High** (NOTE: Can be HIGH <u>only if</u> score-level testing has been conducted)

 \boxtimes \square **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has <u>not</u> been conducted)

 $\Box \boxtimes$ Low (NOTE: Should rate <u>LOW</u> if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

□ **Insufficient** (NOTE: Should rate <u>INSUFFICIENT</u> if you believe you do not have the information you need to make a rating decision)

11. Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.

Panel Member #1 Please see my rationale in 6, 7 and 8.

Panel Member #2 The measure of reliability was not large PIUR=.61 and developers indicated they conducted data element level reliability testing but present no evidence they did so.

Panel Member #3 The methodology was rigorous enough. The results of the reliability analysis were not impressive.

Panel Member #7 Reliability at the score level is low to moderate by the IUR and only slightly higher at the PIUR.

Panel Member #8 Critical data element testing was not submitted although claimed as submitted in 2a2.2. I only see score level testing. See #7 above for more explanation on concerns.

Panel Member #9 This rating is based on IUR results (0.46 for small facility, 0.54 for medium size facility, 0.61 for large facility).

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. Please describe any concerns you have with measure exclusions.

Submission document: Testing attachment, section 2b2. NONE

Panel Member #1 Instead of referring to the Figure 1 in the testing document, it would have been more informative if the measure developer reported sensentivity analyses in a Table and report how SRR changes with elimination of early admissions (on day 0, 1, 2, and so on).

Panel Member #3 No major concerns—except the elimination of information regarding Medicare Advantage patients due to the general lack of quality data for this growing group of Medicare patients.

Panel Member #7 Measure exclusion sizes are provided and constitute about 16.5 % of the population. Specifically, exclusion #6, the hospitalization within 3 days is testing and correlates with the SRR with and without the exclusion. It is concluded that this has face validity and meets the intention of the TEP to address the issues associated with transferring patient support at discharge.

Panel Member #8 The measure flow chart states that readmissions within 3 days are excluded from the revised specs for this submission. This represents 12.2% of the discharges. Figure 1 demonstrates that there are a number of facilities with 0% readmission after application of this new exclusion – no analysis of who/why this is the case. I have a concern that this may be biasing the results and mask opportunities for improvement.

Panel Member #9 No concern.

13. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

Submission document: Testing attachment, section 2b4.

Panel Member #1 The identification of statistically significant and meaningful difference in performance of the measure score hinges on the simulation method described under this section for which very little details have been provided. Reviewers are asked to refer to He et al. (2013); however, the testing document does not have any such reference – the He et al. references mentioned within the testing document are for the years 2019 and 2012 (Unpublished manuscript). I am guessing the measure developer meant the 2012 unpublished manuscript as it described simulation methods, which has later been pulished in Lifetime Data Analysis in 2013). If my guess is true, that specific paper described two methods, and it is not at all clear which of the two methods was applied. In other words, it would have been informative to describe the specific method used for the measure evaluation in the testing document itself. The measure developer argues that the without the empirical null method adopted for identifying outlier facilities takes into account the potential overdispersion and thus avoids flagging a large number of facilities as underperformers; however, without a benchmark, it is difficult to grasp as to how much improvement this method makes compared to the tradtional methods. Lastly, I also wonder how the use of patient-years instead of the number of patients treated in a facility impacted the testing results – it would have been informative if the measure developer presented both sets of results, including "number of patients discharged" as well as "number of patient-years".

Panel Member #2 Developers do not actually present data on the facility scores, range, variation, etc they only show the number/% of facilites, groups in quartiles based on patient years, had scores that were worse than expected based on the facility norms (405 facilities or 5.84%). I am unclear as to what the other scores mean for those who do not perform "worse than expected" or what that cut off rate is? I really need more information.

Panel Member #3 The analyses were conducted for both the critical data elements and for the performance measure score using empirical validity testing. (statement from 2b1.1)

Panel Member #3 Proposed method ("nominal p-value as the probability that the observed number of readmissinos should be at least as extreme as that expected...[that] this facility has a true readmission rate corresponding to the average facility") is less than intuitive and difficult to communicate to likely users of this information to make decisions regarding the choice of dialysis units. (section 2b4).

Panel Member #3 Larger facilities had slightly higher rates of facilities that were worse than expected when compared to smaller facilities. (section 2b4.2)

Panel Member #3 Facilities with higher patient-years (Q4) had higher rates of "worse than expected" (only quartile > 5%). (section 2b4.2)

Panel Member #3 Ability of metric to distinguish meaningful differences within size or patient-years quartiles is not demonstrated.

Panel Member #7 The model allowed the identification of small, medium, and large facilities who had and SRR worse than expected (5.14%, 7.06%, and 8.37%) with an overall idenfication of 6.7%.

Panel Member #9 No concern.

Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified. $N\!/\!A$

Submission document: Testing attachment, section 2b5. N/A Panel Member #3 There were no results provided in section 2b5.

Panel Member #3 Correlations with other related measures (e.g., Standardized Hospitalization Ratio for Admissions) were strong and in the predicted direction. (section 2b1.3)

Panel Member #9 No Concern.

14. Please describe any concerns you have regarding missing data.

Submission document: Testing attachment, section 2b6.

Panel Member #1 Given what has been described in this section with regard to Medicare Advantage patients, I thought it would be helpful if the measure developer conducted a sensitivity analysis, which would entail repeating the analysis using ONLY with traditional fee-for-service Medicare patients. That way, it would have been easier to fathom how the measure performance vary when MA patients are included as part of the measure evaluation.

Panel Member #2 Developers limited the identification of comorbidities to inpatient claims (which are available for patients of all insurance types) and added an adjustment factor to account for Medicare advantage patients in the model. As noted above this is concerning since discharge claims will often only include current relevant dx and not represent a comprehensive documentation of all chronic conditions present. Since all chronic conditions that put patient at higher risk of readmission are included in the risk adjustment model, this means patients will multiple conditions not coded on the discharge claim will not be adjusted for the added risk when applied to the model, resulting in lower expected readmissions that is actually true if one had a full year of history. It takes significant time in claims databases to identify all diagnoses. MOREOVER, based on risk adjustment modeling section for 2019 submission they indicate they use ALL ICD-10 dx codes from each patient's prior year Medicare inpatient claims to estimate the risk adjustment model. It is not clear if they use ALL dx for Medicare FFS patients but only discharge dx for MA patients? Either way this is inconsistent, the model should have utilized only dx available on discharge claims if that is what they are using to calculate the measure rates. If they are using all prior year dx for Medicare and only discharge dx for MA, it will also result in inconsistencies and possibly penalize facilities serving a larger proportion of MA beneficiaries.

Panel Member #3 See previous comments regarding omission of Medicare Advantage patients. Exclusions stated previously seem appropriate.

Panel Member #7 Because of the rise in Medicare Advantage patients as a proportion of Medicare who require dialysis, the ability to gather outpatient comorbidity data is limited. Missing data thus represented the loss of this data which varied by state.

Panel Member #9 No concern.

15. Risk Adjustment

16a. Risk-adjustment method	🗆 None	🛛 Statistical model	□ Stratification
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16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses?

 \Box Yes \Box No \Box \boxtimes Not applicable

16c. Social risk adjustment:

16c.1 Are social risk factors included in risk model?	\Box \boxtimes Yes	🛛 🗆 No 🗆	Not applicable

Panel Member #3 ZIP code level—Area Deprivation Index (ADI) from Census data (2009-2013)

16c.2 Conceptual rationale for social risk factors included? $\Box \boxtimes$ Yes \Box No

16c.3 Is there a conceptual	relationship between potential social risk factor variables and the measure
focus? 🗆 🛛 Yes	🗆 No

16d.Risk adjustment summary:

16d.1 All of the risk-adjustment variables present at the start of care? \square Yes \square No **Panel Member #3** Maybe? Definition of "Time on ESRD" (in years?) not clearly specified. Is this taken only once? What if the patient is on ESRD for multiple years?

16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? □ Yes □ ⊠ No

Panel Member #3 See previous comment

16d.3 Is the risk adjustment approach appropriately developed and assessed? $\Box \boxtimes$ Yes \Box No

Panel Member #3 The information provided is quite extensive.

16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration) □ ☑ Yes □ No

Panel Member #3 ROC (c-statistic) of model is adequate, i.e., "fair" (reported as both 0.6359 and 0.6768)

16d.5.Appropriate risk-adjustment strategy included in the measure? $\Box \boxtimes$ Yes $\boxtimes \Box$ No **Panel Member # 3** See previous comments

16e. Assess the risk-adjustment approach

Panel Member #1

- Baseline diagnoses for the patients are captured from the past year's diagnoses. What happens if patients were newly enrolled in Medicare?
- Measure developer demonstrated that the inclusion of SES in the model changed the flagging
 rates very nominally; however, when one looks at it carefully, about 5.67% or 393 hospitals'
 statuses have changed following the inclusion SES in the risk-adjustment model. In practice, it is
 always a small proportion of hospitals that would get rewarded or penalized. Thus, I would still
 think that the SES adjustment should have been retained in the measure estimation.

Panel Member #2 Though developers make a strong case to include SDH risk factors, and the model resuls shows several are highly significant, they conclude that comparisons of SDH adjusted vs non-SDH adjusted results change facility profiling only nominally. This is in part due to the large number of covariates included in the models. I would also disagree somewhat for the 9 facilities deemed better than expected by non-SDH model ranked as expected by SDH model; the 8 facilities deemed as expected using non-SDH model who performed better than expected in SDH model and the 16 deemed as expected using non-SDH model who were ranked worse than expected after SDH adjustment; and the 10 facilities deemed worse than expected w/o SDH adjustment but deemed as expected (performed better) after SDH adjustment. This is a total of 43 facilities whose rank changes using SDH adjustment. While it is a relatively small proportion of the total number of facilities evaluated, these results could have a big impact on these 43 dialysis facilities. They also state that including SDH adjustment increases the risk of reducing patients' access to high quality care. I would argue it is the OPPOSITE, without appropriately adjusting for higher risk of patients with SDH, facilities may be less likely to take these patients due to impact on performance rates thereby REDUCING access to care.

Panel Member #3 I am willing to give this measure a "pass" given the Developer's clear effort to include socio-demographic risk factors.

Panel Member #7 Observed rates are compared to model-based predictions. All are binned into 20 groups and a c-statistic of 0.6768 obtained from the derived ROC for the SRR model. The Home-Lemeshow test statistic based on deciles of risk was 7.05 with a p-value of 0.5314.

Panel Member #9 Risk-adjustment approach is acceptable.

For cost/resource use measures ONLY:

- 16. Are the specifications in alignment with the stated measure intent?
 - □ Yes □ Somewhat □ No (If "Somewhat" or "No", please explain)
- 17. Describe any concerns of threats to validity related to attribution, the costing approach, carve outs, or truncation (approach to outliers):

VALIDITY: TESTING

18. Validity testing level:
Validity testing

- 19. Method of establishing validity of the measure score:
 - □ Face validity
 - ☑ Empirical validity testing of the measure score
 - □ N/A (score-level testing not conducted)
- 20. Assess the method(s) for establishing validity
 - □ Face validity
 - Empirical validity testing of the measure score
 - □ N/A (score-level testing not conducted)
- 21. Assess the method(s) for establishing validity

Submission document: Testing attachment, section 2b12.

Panel Member #1 Validity testing was conducted through comparisons (e.g., how well-correlated) of this measure with other quality measures in use: standardizd hospitalization ratio (SHR), standandardized mortality ratio (SMR), vascular access – long-term catherter use, vascular access – standardized fistula rate (SFR).

Panel Member #2 Although the developers indicate they conducted data element validity testing, the methods description states "The critical data elements for this measure (hospital admission and discharge dates for Medicare dialysis patients) come from Medicare claims data. The validity of these data is ensured by the oversight of the Medicare program in the payment process." The SMP has determined this is appropriate response, yet given the difference between how model was developed (ie using all ICD-10 for dx during prior year for Medicare population vs. using only ICD-10 dx on discharge claim for Medicare Advantage patients) the effect of that should have been evaluated. It seems most appropriate that the model should have used ONLY dx on discharge claims if that is how it is applied in practice.

Panel Member #3 See comment for item #13.

Panel Member #7 Data validity is based on Medicare claims data and the oversight process.

Panel Member #7 Measure score is tested agains other measures of quality using the Pearson correlation coefficient of SRR to a standardized hospitalization ratio, a standardized mortality ratio, long term vascular catheter rate, and standardized vascular fistula rate.

Panel Member #8 Correlation with SMR and hospitalization ratio much lower than previous submission. SMR, catheter use and fistula use all have low p-values primarily due to the overpowering of the study more than a true measure of validity. The levels of correlation should be interpreted carefully and subjected to clinical relevance review prior to acceptance.

Panel Member #9 The developer conducted empirical validity testing by correlating the measure to four other quality measures: Standardized hospitalization ratio, Standardized mortality ratio, Long-term catheter rate, and Standardized fistula rate.

22. Assess the results(s) for establishing validity

Submission document: Testing attachment, section 2b12.3

Panel Member #1 SRR is a valid measure on the basis of these correlations is at best only moderate.

Panel Member #2 The measure is positively correlated with the one-year Standardized Hospitalization Ratio for Admissions (r = 0.39, p < 0.0001), the Standardized Mortality Ratio (r = 0.10, p < 0.0001), and long term catheter use (r = 0.04, p = 0.0006). The SRR is negatively correlated with the rate of patients using a fistula (r = -0.06, p < 0.0001). The developers note these correlations are very small. I would have liked to see additional validity testing conducted

Panel Member #3 See comment for item #14

Panel Member #7 The expected results were validated with positive correlations to SHR (r =0.39), SMR (r =0.10), and long term catheter use (r =0.04). It is also negatively correlated with fistula rate (r= -0.06).

This supported recommendations from the TEP.

Panel Member #8 Correlation with SMR and hospitalization ratio much lower than previous submission. SMR, catheter use and fistula use all have low p-values primarily due to the overpowering of the study more than a true measure of validity. The levels of correlation should be interpreted carefully and subjected to clinical relevance review prior to acceptance.

Panel Member #9 Resutls for four tests turned out to be as expected, . Althought it is worth noting that the strength of association decreased for all four compared to the results from the initial submission.

23. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?

Submission document: Testing attachment, section 2b1.

 \boxtimes Yes

🗆 No

□ **Not applicable** (score-level testing was not performed)

24. Was the method described and appropriate for assessing the accuracy of ALL critical data elements? *NOTE that data element validation from the literature is acceptable.*

Submission document: Testing attachment, section 2b1.

 $\Box \boxtimes \mathsf{Yes}$

 $\boxtimes \Box$ No

 \square **Not applicable** (data element testing was not performed) – **Panel Member #8** stated it was performed in 2b1, but only state that Medical claims data is valid because it is part of the payment process.

25. OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.

□ High (NOTE: Can be HIGH only if score-level testing has been conducted)

⊠ □ **Moderate** (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

 $\Box \boxtimes$ Low (NOTE: Should rate LOW if you believe that there <u>are</u> threats to validity and/or relevant threats to validity were <u>not assessed OR</u> if testing methods/results are not adequate)

□ **Insufficient** (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level <u>is required</u>; if not conducted, should rate as INSUFFICIENT.)

26. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you may have with the developers' approach to demonstrating validity.

Panel Member #1 The rationale for my low rating is based on what I noted in sections 12, 13, 15, 16 and 22.

Panel Member #2 Concerns outlined above.

Panel Member #3 Given the lack of demonstrated meaningful differences for facilities within quartile groups and the fair c-statistics for the prediction models described, a rating of Low is warranted. The Developer should be commended on the rigorous approach to validity that was presented. Unfortunately, the results of these analyses did not merit a higher rating.

Panel Member #7 At the advice of the TEP, measures of quality were utilized as the the gold standards for validity testing and the results were confirmed.

Panel Member #8 See #22 for concerns about score level validity. Critical data element validity for the registry-based variables not mentioned.

Panel Member #9 This rating is based on the empirical results.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

- 27. What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?
 - 🗌 High
 - □ Moderate
 - □ Low
 - □ Insufficient

28. Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION

ADDITIONAL RECOMMENDATIONS

29. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below.

Panel Member #3 The Developer did provide a summary of concerns expressed by external reviewers that dialysis facilities should not be held responsible for post-care unexpected hospitalization. There was no clear effort to address these concerns. Indeed, the low reliability scores ("half due to within and half due to between") may be emblematic of this underlying problem with the measure.

1. Evidence and Performance Gap – Importance to Measure and Report

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

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

xxxxxxxx.docx

1a.1 <u>For Maintenance of Endorsement:</u> Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

1a. Evidence (subcriterion 1a)

NATIONAL QUALITY FORUM—Evidence (subcriterion 1a)

Measure Number (*if previously endorsed*): 2496

Measure Title: Standardized Readmission Ratio (SRR) for dialysis facilities

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here: Click here to enter composite measure #/ title Date of Submission: Click here to enter a date

Instructions

- Complete 1a.1 and 1a.2 for all measures. If instrument-based measure, complete 1a.3.
- Complete EITHER 1a.2, 1a.3 or 1a.4 as applicable for the type of measure and evidence.
- For composite performance measures:
 - A separate evidence form is required for each component measure unless several components were studied together.
 - If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.
- All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Contact NQF staff regarding questions. Check for resources at <u>Submitting Standards webpage</u>.

<u>Note</u>: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF's evaluation criteria.

1a. Evidence to Support the Measure Focus

The measure focus is evidence-based, demonstrated as follows:

- <u>Outcome</u>: ³ Empirical data demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service. If not available, wide variation in performance can be used as evidence, assuming the data are from a robust number of providers and results are not subject to systematic bias.
- Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured intermediate clinical outcome leads to a desired health outcome.

- <u>Process</u>: ⁵ a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured process leads to a desired health outcome.
- <u>Structure</u>: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence ⁴ that the measured structure leads to a desired health outcome.
- Efficiency: ⁶ evidence not required for the resource use component.
- For measures derived from <u>patient reports</u>, evidence should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.
- <u>Process measures incorporating Appropriate Use Criteria</u>: See NQF's guidance for evidence for measures, in general; guidance for measures specifically based on clinical practice guidelines apply as well.

Notes

- **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.
- 4. The preferred systems for grading the evidence are the Grading of Recommendations, Assessment, Development and Evaluation (<u>GRADE</u>) guidelines and/or modified GRADE.
- 5. Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.
- 6. Measures of efficiency combine the concepts of resource use <u>and</u> quality (see NQF's <u>Measurement Framework: Evaluating</u> <u>Efficiency Across Episodes of Care</u>; <u>AQA Principles of Efficiency Measures</u>).

1a.1.This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

Outcome: hospital 30-day readmission

□Patient-reported outcome (PRO): Click here to name the PRO

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

- □ Intermediate clinical outcome (e.g., lab value): Click here to name the intermediate outcome
- □ Process: Click here to name what is being measured
 - Appropriate use measure: Click here to name what is being measured
- Structure: Click here to name the structure
- Composite: Click here to name what is being measured

1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Original Submission:

The overall aim is to reduce dialysis patients' time in the hospital. Post-discharge care by dialysis facilities—and coordination of that care with other providers—has the potential to prevent hospital readmissions.

2019/2020 Submission:

ESRD chronic dialysis patients are at increased risk of hospital readmission compared to the general population due to disease complexity, treatment impact, greater functional impairments, and overall high comorbidity burden in this population. Preventive interventions such as fluid weight management, management of mineral and bone disease, anemia management as well as post-discharge processes of care (medication reconciliation) by dialysis facilities, and coordination of care with other providers in the pre and post-discharge periods (communication with the dialysis provider; medication reconciliation) have the potential to prevent

hospital readmissions for ESRD dialysis patients. Preventing hospital readmissions is regarded as a shared responsibility that can be impacted by both dialysis providers and hospitals.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

Original Submission:

Studies have shown that pre- and post-discharge interventions may reduce admission and unplanned readmission rates. A variety of studies on non-ESRD populations that evaluated post-discharge interventions (Dunn 1994; Bostrom 1996; Dudas 2001; Azevedo 2002; Coleman 2004; Coleman 2006; Balaban 2008; Braun 2009) or a combination of pre- and post-discharge interventions (Naylor 1994; McDonald 2001; Creason 2001; Ahmed 2004; Anderson 2005; Jack 2009; Koehler 2009; Parry 2009) have indicated a reduction in the risk of unplanned readmissions to various degrees.

In addition, a recent study in the ESRD population found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission (Chan 2009). The author found that three dialysis facility-level process-of-care interventions (Hb testing and modification of EPO dose; MBD testing and modification of vitamin D; and modification of dry weight after discharge) done within the first seven days post-hospital discharge were associated with reduced risk of hospital readmission, adjusted for patient age, sex, race, Charlson comorbidity index, index hospitalization length of stay, time on dialysis, vascular access, diabetes, pre-hospital lab values and the 20 most prevalent causes of hospitalization. Altogether, these studies support the potential for modifying unplanned readmission rates with interventions performed prior to and immediately following patient discharge.

2019/2020 Submission:

Several studies and commentaries strongly suggest pre- and post-discharge interventions within the purview of dialysis providers may reduce the risk of unplanned readmissions within the ESRD chronic dialysis population (Assimon, Wang, and Flythe 2018; Plantinga et al 2018; Flythe et al 2017, 2016; Chan et al 2017; Assimon and Flythe 2017; Plantinga and Jaar 2017). Plantinga et al (2018) found that interventions in the immediate post-discharge period were associated with reduced readmission risk among hemodialysis patients. They also suggest that post-discharge processes of care may help identify certain patients at higher risk for readmission, creating opportunities for dialysis providers to initiate interventions to reduce readmissions. A number of 'patient-at-discharge' characteristics were found by Flythe et al (2017) to be associated with greater readmission risk. These included 10 or more outpatient medications at time of admission; catheter vascular access; three or more hospital admissions in the prior year; and intradialytic hypotension. The authors suggest that modifiable processes of care such as care transitions and targeted medication education may reduce the risk of readmissions among dialysis patients recently discharged. Chan and colleagues (2009) found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission. Assessments included hemoglobin testing and modification of dry weight

after discharge. The risk of unplanned hospital readmission was reduced when these assessments were completed within the first seven days post-hospital discharge. In a commentary (Wish 2014) the Chan 2009 study and several others are cited as examples of the potential for care coordination to reduce readmissions among ESRD dialysis patients. The findings from Chan 2009 are further supported by results from a recent study (Lin et. al. CJASN, 2019) comparing principal diagnosis of index hospitalizations and their associated readmissions. Tables included in the paper's supplementary materials clearly demonstrate that a significant portion of readmission principal discharge diagnoses are for dialysis-related conditions. For example, regardless of the index hospitalization cause (i.e. infectious, endocrine, cardiovascular, Gl, dermatologic, renal, etc), the top principal discharge diagnosis lists for related readmissions prominently included diagnoses typically associated with fluid overload and failure of fluid management in dialysis patients (fluid overload, hypertension, CHF, etc). These results support the early findings from Chan 2009, nearly a decade earlier, showing that adjustment of patient target weight in the early post-hospitalization discharge period (to adjust for the frequent weight loss and/or in-hospital re-assignment of a lower post-dialysis target weight) is a likely mechanism for a substantial minority of unplanned readmissions in the US chronic dialysis population.

Facility structures of care may also impact risk of readmission. One study reported that lower nurses-to-total staff and higher patient-to-nurse ratios were associated with significantly worse 30-day readmission performance (Chen et al 2019).

Finally, findings from the first two performance years of the Center for Medicare and Medicaid Innovation's Comprehensive ESRD Care Initiative suggest care coordination may reduce readmission risk (Marrufo et al, 2019). The findings of this controlled study showed an overall decrease in the percentage of Medicare beneficiaries with at least one readmission, among those aligned to an ESRD Seamless Care Organization, relative to a matched comparison group of facilities

Studies in the non-dialysis setting have cited post-interventions or a combination of pre-and post-discharge interventions as drivers for reducing unplanned readmissions (Dunn 1994; Bostrom 1996; Dudas 2001; Azevedo 2002; Coleman 2004; Coleman 2006; Balaban 2008; Braun 2009; Naylor 1994; McDonald 2001; Creason 2001; Ahmed 2004; Anderson 2005; Jack 2009; Koehler 2009; Parry 2009). However, a recent study and related commentary challenge the reported magnitude of reductions in hospital-wide readmissions since 2010, as part of the publicly reported Hospital Wide Readmission (HWR) measure for the Hospital Readmission Reduction Program (HRRP) (Wadhera, Yeh, and Joynt-Maddox 2019; Ody et al 2019). They suggest the potential driver of these reductions is in part attributed to a change in diagnosis coding policy for inpatient claims that took effect in October 2012. While it is not yet settled whether the reductions were primarily or only nominally driven by the ability of hospitals to report more condition diagnoses, resulting in more robust comorbidity risk adjustment in the measure, the concern has generated attention about whether reported improvements in readmission rates is a result of the HWR and by extension better care delivery by hospitals. These concerns are not considered germane to drivers of readmission reduction based on the dialysis facility readmission measure. The SRR was implemented by CMS in 2015, after the 2012 coding changes took effect. Therefore trends in dialysis patient 30-day readmissions only reflect the period since the claims based diagnoses coding changes, and observed reductions since that time are not considered an artifact of the 2012 inpatient diagnosis coding changes.

Collectively this body of evidence provides support on interventions that may reduce the risk of unplanned readmissions among ESRD dialysis patients. Effective interventions include enhanced care coordination and interventions performed prior to and immediately following the post-discharge period.

Note: Both citations and abstracts have been provided below only for the most recent studies and supporting literature since the SRR was implemented in 2015. Full citations have been provided for literature submitted with the prior submission for original endorsement.

Assimon MM, Flythe JE. Thirty-Day Hospital Readmissions in the Hemodialysis Population: A Problem Well Put, But Half-Solved. Clin J Am Soc Nephrol. 2017 Oct 6;12(10):1566-1568. doi: 10.2215/CJN.08810817. Epub 2017 Sep 28. [editorial, no abstract]

Assimon MM, Wang L, Flythe JE. Failed Target Weight Achievement Associates with Short-Term Hospital Encounters among Individuals Receiving Maintenance Hemodialysis. J Am Soc Nephrol. 2018 Aug;29(8):2178-2188. doi: 10.1681/ASN.2018010004. Epub 2018 May 23.

Background: Hospitalizations and 30-day readmissions are common in the hemodialysis population. Actionable clinical markers for near-term hospital encounters are needed to identify individuals who require swift intervention to avoid hospitalization. Aspects of volume management, such as failed target weight (i.e, estimated dry weight) achievement, are plausible modifiable indicators of impending adverse events. The short-term consequences of failed target weight achievement are not well established.

Methods: Statistically deidentified data were taken from a cohort of Medicare-enrolled, prevalent hemodialysis patients treated at a large dialysis organization from 2010 to 2012. We used a retrospective cohort design with repeated intervals, each consisting of 180-day baseline, 30-day exposure assessment, and 30-day follow-up period, to estimate the associations between failed target weight achievement and the risk of 30-day emergency department visits and hospitalizations. We estimated adjusted risk differences using inverse probability of exposure weighted Kaplan-Meier methods.

Results: A total of 113,561 patients on hemodialysis contributed 788,722 study intervals to analyses. Patients who had a postdialysis weight >1.0 kg above the prescribed target weight in \geq 30% (versus <30%) of exposure period treatments had a higher absolute risk (risk difference) of 30-day: emergency department visits (2.13%; 95% confidence interval, 2.00% to 2.32%); and all-cause (1.47%; 95% confidence interval, 1.34% to 1.62%), cardiovascular (0.31%; 95% confidence interval, 0.24% to 0.40%), and volume-related (0.15%; 95% confidence interval, 0.11% to 0.21%) hospitalizations. Conclusions: In the absence of objective measures of volume status, recurrent failure to achieve target weight is an easily identifiable clinical risk marker for impending hospital encounters among patients on hemodialysis.

Chan L, Chauhan K, Poojary P, Saha A, Hammer E, Vassalotti JA, Jubelt L, Ferket B, Coca SG, Nadkarni GN. National Estimates of 30-Day Unplanned Readmissions of Patients on Maintenance Hemodialysis. Clin J Am Soc Nephrol. 2017 Oct 6;12(10):1652-1662. doi: 10.2215/CJN.02600317. Epub 2017 Sep 28.

BACKGROUND AND OBJECTIVES: Patients on hemodialysis have high 30-day unplanned readmission rates. Using a national all-payer administrative database, we describe the epidemiology of 30-day unplanned readmissions in patients on hemodialysis, determine concordance of reasons for initial admission and readmission, and identify predictors for readmission.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: This is a retrospective cohort study using the Nationwide Readmission Database from the year 2013 to identify index admissions and readmission in patients with ESRD on hemodialysis. The Clinical Classification Software was used to categorize admission diagnosis into mutually exclusive clinically meaningful categories and determine concordance of reasons for admission on index hospitalizations and readmissions. Survey logistic regression was used to identify predictors of at least one readmission.

RESULTS: During 2013, there were 87,302 (22%) index admissions with at least one 30-day unplanned readmission. Although patient and hospital characteristics were statistically different between those with and without readmissions, there were small absolute differences. The highest readmission rate was for acute myocardial infarction (25%), whereas the lowest readmission rate was for hypertension (20%). The primary reasons for initial hospitalization and subsequent 30-day readmission were

discordant in 80% of admissions. Comorbidities that were associated with readmissions included depression (odds ratio, 1.10; 95% confidence interval [95% CI], 1.05 to 1.15; P<0.001), drug abuse (odds ratio, 1.41; 95% CI, 1.31 to 1.51; P<0.001), and discharge against medical advice (odds ratio, 1.57; 95% CI, 1.45 to 1.70; P<0.001). A group of high utilizers, which constituted 2% of the population, was responsible for 20% of all readmissions.

CONCLUSIONS: In patients with ESRD on hemodialysis, nearly one quarter of admissions were followed by a 30-day unplanned readmission. Most readmissions were for primary diagnoses that were different from initial hospitalization. A small proportion of patients accounted for a disproportionate number of readmissions.

Chan K, Lazarus JM, Wingard R, and Hakim R. Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge. Kidney International. Kidney International (2009) 76, 331–341.

Dialysis patients have a greater number of hospitalization events compared to patients without renal failure. Here we studied the relationship between different post-discharge interventions and repeat hospitalization in over 126,000 prevalent hemodialysis patients to explore outpatient strategies that minimize the risk of repeat hospitalization. The primary outcome was repeat hospitalization within 30 days of discharge. Compared to pre-hospitalization values, the levels of hemoglobin, albumin, phosphorus, calcium, and parathyroid hormone and weight were significantly decreased after hospitalization. Using covariate-adjusted models, those patients whose hemoglobin was monitored within the first 7 days after discharge, followed by modification of their erythropoietin dose had a significantly reduced risk for repeat-hospitalization when compared to the patients whose hemoglobin was not checked, nor was the dose of erythropoietin changed. Similarly, administration of vitamin D within the 7 days following discharge was significantly associated with reduced repeat hospitalization when compared to patients on no vitamin D. Therefore, it appears that immediate re-evaluation of anemia management orders and resumption of vitamin D soon after discharge may be an effective way to reduce repeat hospitalization.

Chen Y, Rhee C, Senturk D, Kurum E, Campos L, Li Y, Kalantar-Zadeh K, Nguyen D. Association of US Dialysis Facility Staffing with Profiling of Hospital-Wide 30-Day Unplanned Readmission. Kidney Dis (Basel). 2019 Jun;5(3):153-162. doi: 10.1159/000496147. Epub 2019 Feb 5.

BACKGROUND: Unplanned hospital readmissions are a major source of morbidity among dialysis patients, in whom the risk of hospital readmission is exceptionally high. The contribution of dialysis facility staffing to hospital readmission has been largely overlooked. METHODS: Using annual data of dialysis patients from the United States Renal Data System from 2010 to 2013, we assessed dialysis facilities with a significantly worse (SW) and facilities with a nonsignificant (NS) standardized readmission ratio (SRR). SRR estimates were risk adjusted for patient factors, past year comorbidities, and index hospitalization characteristics. Facility staffing variables were compared between 2 exposure groups: facilities with SW and NS SRRs. Four measures of staffing, including patient-to-staffing ratio, were compared between SW and matched NS facilities. RESULTS: About 136,000-148,000 dialysis patients with 269,000-319,000 index hospital discharges were used to identify facilities with SW and facilities with NS SRR annually. Approximately 3-4% of facilities were identified as having SW SRR among > 5,000 facilities annually. The percent of nurses-tototal staff was significantly lower in 2010 for SW facilities than in matched NS facilities (42.5 vs. 45.6%, p = 0.012), but this disparity was attenuated by 2013 (44.8 vs. 44.7%, p = 0.949). There was a higher patient-to-nurse ratio for SW facilities than for NS facilities (mean 16.4 vs. 15.2, p = 0.038) in 2010 as well, and the disparity was reduced by 2013. The trends were similar for patient-to-total staff and patient-to-registered nurse, but not statistically significant.

CONCLUSIONS: This study found that dialysis facilities with SW 30-day readmission rates had lower proportions of nurses-to-total staff and higher patient-to-nurse ratios, but this disparity improved in recent years. Additional research is warranted focusing on how evidence-based staffing at dialysis facilities can contribute to reduction of hospital readmission, and this knowledge is needed to inform clinical practice guidelines and policy decisions regarding optimal dialysis patient staffing.

Erickson KF, Kurella Tamura M. Overlooked care transitions: an opportunity to reduce acute care use in ESRD. Clin J Am Soc Nephrol. 2015 Mar 6;10(3):347-9. doi: 10.2215/CJN.00220115. Epub 2015 Feb 3. Comment on Clin J Am Soc Nephrol. 2015 Mar 6;10(3):428-34.

Estes JP, Chen Y, Şentürk D, Rhee CM, Kürüm E, You AS, Streja E, Kalantar-Zadeh K, Nguyen DV. Profiling dialysis facilities for adverse recurrent events. Stat Med. 2020 Jan 30. doi: 10.1002/sim.8482. doi: 10.1002/sim.8482. [Epub ahead of print]

Profiling analysis aims to evaluate health care providers, such as hospitals, nursing homes, or dialysis facilities, with respect to a patient outcome. Previous profiling methods have considered binary outcomes, such as 30-day hospital readmission or mortality. For the unique population of dialysis patients, regular blood works are required to evaluate effectiveness of treatment and avoid adverse events, including dialysis inadequacy, imbalance mineral levels, and anemia among others. For example, anemic events (when hemoglobin levels exceed normative range) are recurrent and common for patients on dialysis. Thus, we propose high-dimensional Poisson and negative binomial regression models for rate/count outcomes and introduce a standardized event ratio measure to compare the event rate at a specific facility relative to a chosen normative standard, typically defined as an "average" national rate across all facilities. Our proposed estimation and inference procedures overcome the challenge of high-dimensional parameters for thousands of dialysis facilities. Also, we investigate how overdispersion affects inference in the context of profiling analysis. The proposed methods are illustrated with profiling dialysis facilities for recurrent anemia events.

Estes JP, Nguyen DV, Chen Y, Dalrymple LS, Rhee CM, Kalantar-Zadeh K, Şentürk D. Time-dynamic profiling with application to hospital readmission among patients on dialysis. Biometrics. 2018 Dec;74(4):1383-1394. doi: 10.1111/biom.12908. Epub 2018 Jun 5.

Standard profiling analysis aims to evaluate medical providers, such as hospitals, nursing homes, or dialysis facilities, with respect to a patient outcome. The outcome, for instance, may be mortality, medical complications, or 30-day (unplanned) hospital readmission. Profiling analysis involves regression modeling of a patient outcome, adjusting for patient health status at baseline, and comparing each provider's outcome rate (e.g., 30-day readmission rate) to a normative standard (e.g., national "average"). Profiling methods exist mostly for non time-varying patient outcomes. However, for patients on dialysis, a unique population which requires continuous medical care, methodologies to monitor patient outcomes continuously over time are particularly relevant. Thus, we introduce a novel time-dynamic profiling (TDP) approach to assess the time-varying 30-day readmission rate. TDP is used to estimate, for the first time, the risk-standardized time-dynamic 30-day hospital readmission rate, throughout the time period that patients are on dialysis. We develop the framework for TDP by introducing the standardized dynamic readmission ratio as a function of time and a multilevel varying coefficient model with facility-specific time-varying effects. We propose estimation and inference procedures tailored to the problem of TDP and to overcome the challenge of high-dimensional parameters when examining thousands of dialysis facilities.

Flythe JE, Hilbert J, Kshirsagar AV, Gilet CA. Psychosocial Factors and 30-Day Hospital Readmission among Individuals Receiving Maintenance Dialysis: A Prospective Study. Am J Nephrol. 2017;45(5):400-408. doi: 10.1159/000470917. Epub 2017 Apr 14.

BACKGROUND: Thirty-day hospital readmissions are common among maintenance dialysis patients. Prior studies have evaluated easily measurable readmission risk factors such as comorbid conditions, laboratory results, and hospital discharge day. We undertook this prospective study to investigate the associations between hospital-assessed depression, health literacy, social support, and self-rated health (separately) and 30-day hospital readmission among dialysis patients. METHODS: Participants were recruited from the University of North Carolina Hospitals, 2014-2016. Validated depression, health literacy, social support, and self-rated health screening instruments were administered during index hospitalizations. Multivariable logistic regression models with 30-day readmission as the dependent outcome were used to examine readmission risk factors. RESULTS: Of the 154 participants, 58 (37.7%) had a 30-day hospital readmission. In unadjusted analyses, individuals with positive screening for depression, lower health literacy, and poorer social support were more likely to have a 30-day readmission (vs. negative screening). Positive depression screening and poorer social support remained significantly associated with 30-day readmission in models adjusted for race, heart failure, admitting service, weekend discharge day, and serum albumin: adjusted OR (95% CI) 2.33 (1.02-5.15) for positive depressive symptoms and 2.57 (1.10-5.91) for poorer social support. The area under the receiver operating characteristic curve (AUC) of the multivariable model adjusted for social support status was significantly greater than the AUC of the multivariable model without social support status (test for equality; p value = 0.04). CONCLUSION: Poor social support and depressive symptoms identified during hospitalizations may represent targetable readmission risk factors among dialysis patients. Our findings suggest that hospital-based assessments of select psychosocial factors may improve readmission risk prediction.

Flythe JE, Katsanos SL, Hu Y, Kshirsagar AV, Falk RJ, Moore CR. Predictors of 30-Day Hospital Readmission among Maintenance Hemodialysis Patients: A Hospital's Perspective. Clin J Am Soc Nephrol. 2016 Jun 6;11(6):1005-14. doi: 10.2215/CJN.11611115. Epub 2016 May 5.

BACKGROUND AND OBJECTIVES: Over 35% of patients on maintenance dialysis are readmitted to the hospital within 30 days of hospital discharge. Outpatient dialysis facilities often assume responsibility for readmission prevention. Hospital care and discharge practices may increase readmission risk. We undertook this study to elucidate risk factors identifiable from hospital-derived data for 30-day readmission among patients on hemodialysis.

DESIGN, SETTING, PARTICIPANTS, & MEASUREMENTS: Data were taken from patients on maintenance hemodialysis discharged from University of North Carolina Hospitals between May of 2008 and June of 2013 who received in-patient hemodialysis during their index hospitalizations. Multivariable logistic regression models with 30-day readmission as the dependent outcome were used to identify readmission risk factors. Models considered variables available at hospital admission and discharge separately.

RESULTS: Among 349 patients, 112 (32.1%) had a 30-day hospital readmission. The discharge (versus admission) model was more predictive of 30-day readmission. In the discharge model, malignancy comorbid condition (odds ratio [OR], 2.08; 95% confidence interval [95% CI], 1.04 to 3.11), three or more hospitalizations in the prior year (OR, 1.97; 95% CI, 1.06 to 3.64), \geq 10 outpatient medications at hospital admission (OR, 1.69; 95% CI, 1.00 to 2.88), catheter vascular access (OR, 1.82; 95% CI, 1.01 to 3.65), outpatient dialysis at a nonuniversity-affiliated dialysis facility (OR, 3.59; 95% CI, 2.03 to 6.36), intradialytic hypotension (OR, 3.10; 95% CI, 1.45 to 6.61), weekend discharge day (OR, 1.82; 95% CI, 1.01 to 3.31), and serum albumin <3.3 g/dl (OR, 4.28; 95% CI, 2.37 to 7.73) were associated with higher readmission odds. A decrease in prescribed medications from admission to discharge (OR, 0.20;

95% Cl, 0.08 to 0.51) was associated with lower readmission odds. Findings were robust across different model-building approaches.

CONCLUSIONS: Models containing discharge day data had greater predictive capacity of 30-day readmission than admission models. Identified modifiable readmission risk factors suggest that improved medication education and improved transitions from hospital to community may potentially reduce readmissions. Studies evaluating targeted transition programs among patients on dialysis are needed.

Kindy J, Roer D, Wanovich R, McMurray S. A payer-provider partnership for integrated care of patients receiving dialysis. Am J Manag Care. 2018 Apr;24(4):204-208.

OBJECTIVES: Patients with end-stage renal disease (ESRD) are clinically complex, requiring intensive and costly care. Coordinated care may improve outcomes and reduce costs. The objective of this study was to determine the impact of a payer-provider care partnership on key clinical and economic outcomes in enrolled patients with ESRD.

STUDY DESIGN: Retrospective observational study.

METHODS: Data on patient demographics and clinical outcomes were abstracted from the electronic health records of the dialysis provider. Data on healthcare costs were collected from payer claims. Data were collected for a baseline period prior to initiation of the partnership (July 2011-June 2012) and for two 12-month periods following initiation (April 2013-March 2014 and April 2014-March 2015).

RESULTS: Among both Medicare Advantage and commercial insurance program members, the rate of central venous catheter use for vascular access was lower following initiation of the partnership compared with the baseline period. Likewise, hospital admission rates, emergency department visit rates, and readmission rates were lower following partnership initiation. Rates of influenza and pneumococcal vaccination were higher than 95% throughout all 3 time periods. Total medical costs were lower for both cohorts of members in the second 12-month period following partnership initiation compared with the baseline period.

CONCLUSIONS: Promising trends were observed among members participating in this payer-provider care partnership with respect to both clinical and economic outcomes. This suggests that collaborations with shared incentives may be a valuable approach for patients with ESRD.

Marrufo G, Negrusa B, Ullman D, Hirth R, Messana J, Maughan B, Nelson J, Lindsey N, Gregory D, Svoboda R, Melin C, Chung A, Dahlerus C, Nahra T, Jiao A, McKeithen K, and Gilfix Z. Comprehensive End-Stage Renal Disease Care (CEC) Model Performance Year 2 Annual Evaluation Report. Prepared for: Centers for Medicare & Medicaid Services. September 2019. [No abstract available] https://innovation.cms.gov/Files/reports/cec-annrpt-py2.pdf

Lin E, Kurella Tamura M, Montez-Rath ME, Chertow GM. Re-evaluation of re-hospitalization and rehabilitation in renal research. Hemodial Int. 2017 Jul;21(3):422-429. doi: 10.1111/hdi.12497. Epub 2016 Oct 20.

INTRODUCTION: The use of administrative data to capture 30-day readmission rates in end-stage renal disease is challenging since Medicare combines claims from acute care, inpatient rehabilitation (IRF), and long-term care hospital stays into a single "Inpatient" file. For data prior to 2012, the United States Renal Data System does not contain the variables necessary to easily identify different facility types, making it likely that prior studies have inaccurately estimated 30-day readmission rates. METHODS: For this report, we developed two methods (a "simple method" and a "rehabilitation-adjusted method") to identify acute care, IRF, and long-term care hospital stays from United States Renal Data System claims data, and compared them to methods used in previously published reports.

FINDINGS: We found that prior methods overestimated 30-day readmission rates by up to 12.3% and overestimated average 30-day readmission costs by up to 11%. In contrast, the simple and rehabilitation-adjusted methods overestimated 30-day readmission rates by 0.1% and average 30-day readmission costs by 1.8%. The rehabilitation-adjusted method also accurately identified 96.8% of IRF stays.

DISCUSSION: Prior research has likely provided inaccurate estimates of 30-day readmissions in patients undergoing dialysis. In the absence of data on specific facility types particularly when using data prior to 2012, future researchers could employ our method to more accurately characterize 30-day readmission rates and associated outcomes in patients with end-stage renal disease.

Lin E, Bhattacharya J, and Chertow GM. Prior Hospitalization Burden and the Relatedness of 30-Day Readmissions in Patients Receiving Hemodialysis. J Am Soc Nephrol 30: ccc–ccc, 2019

Background: Thirty-day readmissions are common in patients receiving hemodialysis and costly to Medicare. Because patients on hemodialysis have a high background hospitalization rate, 30-day readmissions might be less likely related to the index hospitalization than in patients with other conditions.

Methods: In adults with Medicare receiving hemodialysis in the United States, we used multinomial logistic regression to evaluate whether prior hospitalization burden was associated with increased 30-day readmissions unrelated to index hospitalizations with a discharge date from January 1, 2013 to December 31, 2014. We categorized a hospitalization, 30-day readmission pair as "related" if the principal diagnoses came from the same organ system.

Results: The adjusted probability of unrelated 30-day readmission after any index hospitalization was 19.1% (95% confidence interval [95% CI] 18.9% to 19.3%), 22.6% (95% CI, 22.4% to 22.8%), and 31.2% (95% CI, 30.8% to 31.5%) in patients with 0–1, 2–4, and \$5 hospitalizations, respectively. Cardiovascular index hospitalizations had the highest adjusted probability of related 30-day readmission: 10.4% (95% CI, 10.2% to 10.7%), 13.6% (95% CI, 13.4% to 13.9%), and 20.8% (95% CI, 20.2% to 21.4%), respectively. Renal index hospitalizations had the lowest adjusted probability of related 30-day readmission: 2.0% (95% CI, 1.8% to 2.3%), 3.9% (95% CI, 3.4% to 4.4%), and 5.1% (95% CI, 4.3% to 5.9%), respectively.

Conclusions: High prior hospitalization burden increases the likelihood that patients receiving hemodialysis experience a 30-day readmission unrelated to the index hospitalization. Health care payers such as Medicare should consider incorporating clinical relatedness into 30-day readmission quality measures.

Ody C, Msall L, Dafny L, Grabowski D, and Cutler D. Decreases In Readmissions Credited To Medicare's Program To Reduce Hospital Readmissions Have Been Overstated. Health Affairs, 38, No. 1 (2019):36–43. Medicare's Hospital Readmissions Reduction Program (HRRP) has been credited with lowering riskadjusted readmission rates for targeted conditions at general acute care hospitals. However, these reductions appear to be illusory or overstated. This is because a concurrent change in electronic transaction standards allowed hospitals to document a larger number of diagnoses per claim, which had the effect of reducing risk-adjusted patient readmission rates. Prior studies of the HRRP relied upon control groups' having lower baseline readmission rates, which could falsely create the appearance that readmission rates are changing more in the treatment than in the control group. Accounting for the revised standards reduced the decline in risk-adjusted readmission rates for targeted conditions by 48 percent. After further adjusting for differences in pre-HRRP readmission rates across samples, we found that declines for targeted conditions at general acute care hospitals were statistically indistinguishable from declines in two control samples. Either the HRRP had no effect on readmissions, or it led to a system wide reduction in readmissions that was roughly half as large as prior estimates have suggested. Perl J, McArthur E, Bell C, et al. Dialysis Modality and Readmission Following Hospital Discharge: A Population-Based Cohort Study. AJKD, 2016, epub.

Background: Readmissions following hospital discharge among maintenance dialysis patients are common, potentially modifiable, and costly. Compared with patients receiving in-center hemodialysis (HD), patients receiving peritoneal dialysis (PD) have fewer routine dialysis clinic encounters and as a result may be more susceptible to a hospital readmission following discharge.

Study design: Population-based retrospective-cohort observational study.

Settings & participants: Patients treated with maintenance dialysis who were discharged following an acute-care hospitalization during January 1, 2003, to December 31, 2013, across 164 acute-care hospitals in Ontario, Canada. For those with multiple hospitalizations, we randomly selected a single hospitalization as the index hospitalization.

Predictor: Dialysis modality PD or in-center HD. Propensity scores were used to match each patient on PD therapy to 2 patients on in-center HD therapy to ensure that baseline indicators of health were similar between the 2 groups.

Outcome: All-cause 30-day readmission following the index hospital discharge.

Results: 28,026 dialysis patients were included in the study. 4,013 PD patients were matched to 8,026 in-center HD patients. Among the matched cohort, 30-day readmission rates were 7.1 (95% CI, 6.6-7.6) per 1,000 person-days for patients on PD therapy and 6.0 (95% CI, 5.7-6.3) per 1,000 person-days for patients on in-center HD therapy. The risk for a 30-day readmission among patients on PD therapy was higher compared with those on in-center HD therapy (adjusted HR, 1.19; 95% CI, 1.08-1.31). The primary results were consistent across several key prespecified subgroups.

Limitations: Lack of information for the frequency of nephrology physician encounters following discharge from the hospital in both the PD and in-center HD cohorts. Limited validation of International Classification of Diseases, Tenth Revision codes.

Conclusions: The risk for 30-day readmission is higher for patients on home-based PD compared to incenter HD therapy. Interventions to improve transitions in care between the inpatient and outpatient settings are needed, particularly for patients on PD therapy.

Plantinga LC, Jaar BG. On the Right Track: Implementing Interventions to Reduce Readmissions in Dialysis Patients. Am J Nephrol. 2017;45(6):549-551. doi: 10.1159/000477100. Epub 2017 May 25. [editorial]

Plantinga LC, Masud T, Lea JP, Burkart JM, O'Donnell CM, Jaar BG. Post-hospitalization dialysis facility processes of care and hospital readmissions among hemodialysis patients: a retrospective cohort study. BMC Nephrol. 2018 Jul 31;19(1):186. doi: 10.1186/s12882-018-0983-5.

BACKGROUND: Both dialysis facilities and hospitals are accountable for 30-day hospital readmissions among U.S. hemodialysis patients. We examined the association of post-hospitalization processes of care at hemodialysis facilities with pulmonary edema-related and other readmissions. METHODS: In a retrospective cohort comprised of electronic medical record (EMR) data linked with national registry data, we identified unique patient index admissions (n = 1056; 2/1/10-7/31/15) that were followed by \geq 3 in-center hemodialysis sessions within 10 days, among patients treated at 19 Southeastern dialysis facilities. Indicators of processes of care were defined as present vs. absent in the dialysis facility EMR. Readmissions were defined as admissions within 30 days of the index discharge; pulmonary edema-related vs. other readmissions defined by discharge codes for pulmonary edema, fluid overload, and/or congestive heart failure. Multinomial logistic regression to estimate odds ratios (ORs) for pulmonary edema-related and other vs. no readmissions. RESULTS: Overall, 17.7% of patients were readmitted, and 8.0% had pulmonary edema-related readmissions (44.9% of all readmissions). Documentation of the index admission (OR = 2.03, 95% CI 1.07-3.85), congestive heart failure (OR = 1.87, 95% CI 1.07-3.27), and home medications stopped (OR = 1.81, 95% CI 1.08-3.05) or changed (OR = 1.69, 95% CI 1.06-2.70) in the EMR post-hospitalization were all associated with higher risk of pulmonary edema-related vs. no readmission; lower post-dialysis weight (by \geq 0.5 kg) after vs. before hospitalization was associated with 40% lower risk (OR = 0.60, 95% CI

0.37-0.96).

CONCLUSIONS: Our results suggest that some interventions performed at the dialysis facility in the post-hospitalization period may be associated with reduced readmission risk, while others may provide a potential existing means of identifying patients at higher risk for readmissions, to whom such interventions could be efficiently targeted.

Reilly JB, Marcotte LM, Berns JS, Shea JA. Handoff communication between hospital and outpatient dialysis units at patient discharge: a qualitative study. Jt Comm J Qual Patient Saf. 2013 Feb;39(2):70-6.

BACKGROUND: Hemodialysis patients are vulnerable to adverse events, including those surrounding hospital discharge. Little is known about how dialysis-specific information is shared with outpatient dialysis clinics for discharged patients, and the applicability of existing models of handoff transitions is unknown.

METHODS: Semistructured interviews were performed with 36 dialysis care physicians, nurses, and social workers in hospital and outpatient settings. Interviews were transcribed and qualitatively analyzed by trained coders. Intercoder reliability was measured by Cohen's kappa FINDINGS: Quality of communication and the actual process were highly variable. Good communication was described as timely, with standardized content, and coordinated between disciplines. A lack of standards, time/workload imbalance, incompatible electronic records between facilities, and unawareness of pending discharge plans were noted barriers to good communication. Poor or absent communication contributes to adverse events, including omission of antibiotics, mismanagement of congestive heart failure, readmissions, and loss of patient trust. Creating explicit standards for communication, fostering accountability, documenting receipt in the outpatient clinic, and continual feedback from outpatient to inpatient settings are methods to facilitate improvement and reduce preventable adverse events.

CONCLUSIONS: Standardizing the communication process between inpatient and outpatient dialysis units when patients are discharged from the hospital has potential to reduce adverse events related to poor communication and improve patient care during this transition. Interprofessional collaboration has potential to create robust solutions to this complex problem and foster a culture of multidisciplinary reflexivity.

Ross KH, Jaar BG, Lea JP, Masud T, Patzer RE, Plantinga LC. Long-term outcomes among Medicare patients readmitted in the first year of hemodialysis: a retrospective cohort study. BMC Nephrol. 2019 Jul 29;20(1):285. doi: 10.1186/s12882-019-1473-0.

BACKGROUND: Readmission within 30 days of hospital discharge is common and costly among endstage renal disease (ESRD) patients. Little is known about long-term outcomes after readmission. We estimated the association between hospital admissions and readmissions in the first year of dialysis and outcomes in the second year.

METHODS: Data on incident dialysis patients with Medicare coverage were obtained from the United States Renal Data System (USRDS). Readmission patterns were summarized as no admissions in the first year of dialysis (Admit-), at least one admission but no readmissions within 30 days (Admit+/Readmit-), and admissions with at least one readmission within 30 days

(Admit+/Readmit+).We used Cox proportional hazards models to estimate the association between readmission pattern and mortality, hospitalization, and kidney transplantation, accounting for demographic and clinical covariates.

RESULTS: Among the 128,593 Medicare ESRD patients included in the study, 18.5% were Admit+/Readmit+, 30.5% were Admit+/Readmit-, and 51.0% were Admit-. Readmit+/Admit+ patients had substantially higher long-term risk of mortality (HR = 3.32 (95% CI, 3.21-3.44)), hospitalization (HR = 4.46 (95% CI, 4.36-4.56)), and lower likelihood of kidney transplantation (HR = 0.52 (95% CI, 0.44-0.62)) compared to Admit- patients; these associations were stronger than those among Admit+/Readmit- patients.

CONCLUSIONS: Patients with readmissions in the first year of dialysis were at substantially higher risk of poor outcomes than either patients who had no admissions or patients who had hospital admissions but no readmissions. Identifying strategies to both prevent readmission and mitigate risk among patients who had a readmission may improve outcomes among this substantial, high-risk group of ESRD patients.

Shen JI, Dave NN, Erickson KF. Home Alone: Does Modality Matter? Revisiting Hospital Readmissions in Dialysis. Am J Kidney Dis. 2017 Jul;70(1):1-3. doi: 10.1053/j.ajkd.2017.04.006. [editorial]

Wadhera R, Yeh R, and Maddox KJ. The Hospital Readmissions Reduction Program — Time for a Reboot. Perspective article. N Engl J Med 2019; 380:2289-2291. [no abstract – Perspective article]

Wetmore JB, Molony JT, Liu J, Peng Y, Herzog CA, Collins AJ, Gilbertson DT. Readmissions Following a Hospitalization for Cardiovascular Events in Dialysis Patients: A Retrospective Cohort Study. J Am Heart Assoc. 2018 Feb 13;7(4):e007231. doi: 10.1161/JAHA.117.007231.

BACKGROUND: Hospitalization for cardiovascular disease (CVD) is common among patients receiving maintenance dialysis, but patterns of readmissions following cardiovascular events are underexplored. METHODS AND RESULTS: In this retrospective analysis of prevalent, Medicare-eligible patients receiving dialysis in 2012-2013, all live-discharge hospitalizations attributed to CVD were ascertained. Rates of all-cause, CVD-related, and non-CVD-related readmissions and death in the ensuing 10 and 30 days were calculated. Multinomial logistic modeling was used to assess the relationship between potential explanatory factors and outcomes of interest. Among 142 210 analyzed hospitalizations, mean age at time of index CVD hospitalization was 64.9±14.1 years; 50.4% of index hospitalizations were for women, and 41.4% were for white patients. Fully 15.6% and 34.2% of CVD hospitalizations resulted in readmission within 10 and 30 days, respectively; less than half of readmissions were CVD related (42.5%, 10 days; 43.1%, 30 days). Death within 30 days, regardless of readmission, occurred after 4.5% of index hospitalizations; 51.2% were attributed to CVD. Compared with ages 65 to 69 years, younger age tended to be associated with increased readmission risk (adjusted relative risk for ages 18-44 years: 1.55; 95% confidence interval, 1.48-1.63). Readmission risk did not differ between white and black patients, but risk of death without readmission was markedly lower for black patients (relative risk: 0.60; 95% confidence interval, 0.55-0.67).

CONCLUSIONS: Roughly 1 in 3 CVD hospitalizations resulted in 30-day readmission; nearly 1 in 20 was followed by death within 30 days. Risk of death without readmission was higher for white than black patients, despite no difference in risk of readmission.

Wish JB. The role of 30-day readmission as a measure of quality. Clin J Am Soc Nephrol. 2014 Mar;9(3):440-2. doi: 10.2215/CJN.00240114. Epub 2014.

Hospital readmissions among dialysis patients are a significant burden for patients and the healthcare system. In 2010, patients receiving hemodialysis were admitted to the hospital an average of nearly two times per year, 36% of whom were rehospitalized within 30 days (1). As Springel et al. demonstrate in this issue of CJASN (2), hospital readmissions occur frequently with pediatric patients with ESRD as well as with their adult counterparts. Data from the US Renal Data System show the highest rate of hospital readmissions among ... PMCID: PMC3944749 [Available on 2015/3/7] PMID: 24509293 [PubMed - in process]

Citations from Original Submission:

- Ahmed A, Thornton P, Perry GJ, Allman RM, DeLong JF. Impact of atrial fibrillation on mortality and readmission in older adults hospitalized with heart failure. Eur J Heart Fail. 2004;6(4):421-426.
- Anderson MA, Clarke MM, Helms LB, Foreman MD. Hospital readmission from home health care before and after prospective payment. J Nurs Scholarsh. 2005;37(1):73-79.
- Azevedo A, Pimenta J, Dias P, Bettencourt P, Ferreira A, Cerqueira-Gomes M. Effect of a heart failure clinic on survival and hospital readmission in patients discharged from acute hospital care. Eur J Heart Fail. 2002 Jun;4(3):353-359.
- Balaban RB, Weissman JS, Samuel PA, Woolhandler S. Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study. J Gen Intern Med. 2008;23(8):1228-1233.
- Bostrom J, Caldwell J, McGuire K, Everson D. Telephone follow-up after discharge from the hospital: Does it make a difference? Appl Nurs Res. 1996;9:47-52.
- Braun E, Baidusi A, Alroy G, Azzam ZS. Telephone follow-up improves patients satisfaction following hospital discharge. Eur J Internal Med. 2009;20:221-225.
- Chan K, Lazarus M, Wingard R, et al. "Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge." Kidney International (2009) 76:331-41.
- Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: the Care Transitions Intervention. J Am Geriatr Soc. 2004 Nov;52(11):1817-25.
- Coleman E, Parry C, Chalmers S, et al. The care transitions intervention. Arch Internal Med. 2006;166:1822-1828.
- Creason H. Congestive heart failure telemanagement clinic. Lippencotts Case Management: Managing the Process of Patient Care. 2001 Jul-Aug;6(4):146-56.
- Dudas V, Bookwalter T, Kerr KM et al. The impact of follow-up telephone calls to patients after hospitalization. American Journal of Medicine. 2001; 111(9B):26S-30S
- Dunn JM, Elliot TB, Lavy JA et al. Outpatient clinic review after arterial reconstruction: is it necessary? Annals of the Royal College of Surgeons of England. 1994 Sep;76(5):304-6.

- Jack B, Chetty V, Anthony D, et al. "A reengineered hospital discharge program to decrease rehospitalizaton. " Annals of Internal Medicine (2009) 150:178-88.
- Koehler BE, Richter KM, Youngblood L et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. Journal of Hospital Medicine. 2009 Apr;4(4):211-8.
- McDonald, MD. The hospitalist movement: wise or wishful thinking? Nurse management. 2001 Mar;32(3):30-1.
- Naylor M, Brooten D, Jones R et al. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Annals of Internal Medicine. 1994 Jun 15;120(12):999-1006.
- Parry C, Min SH, Chugh A et al. Further application of the care transitions intervention: results of a randomized controlled trial conducted in a fee-for-service setting. Home Health Care Services Quarterly. 2009;28(2-3):84-99.

1a.3. SYSTEMATIC REVIEW(SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the <u>systematic review of the body of evidence</u> that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

□ Clinical Practice Guideline recommendation (with evidence review)

US Preventive Services Task Force Recommendation

□ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other

Source of Systematic Review:	N/A
• Title	
Author	
• Date	
Citation, including page number	
• URL	
Quote the guideline or recommendation	N/A
verbatim about the process, structure	
or intermediate outcome being	
measured. If not a guideline,	

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

N/A

1a.4.2 What process was used to identify the evidence?

N/A

1a.4.3. Provide the citation(s) for the evidence.

N/A

1b. Performance Gap

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

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

1b.1. Briefly explain the rationale for this measure (*e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure*)

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

Unplanned readmission rates are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and hospitalizations account for approximately 38% of total Medicare expenditures for dialysis patients (U.S. Renal Data System, 2018). In 2010, 37% of dialysis patient discharges from an all-cause hospitalization were followed by an unplanned readmission within 30 days (U.S. Renal Data System, 2018). Measures of the frequency of unplanned readmissions, such as SRR, help efforts to control escalating medical costs, play an important role in providing cost-effective health care, and support coordination of care across inpatient and outpatient settings. Preventive interventions such as fluid weight management, management of mineral and bone disease, anemia management as well as post-discharge processes of care (medication reconciliation) by dialysis facilities, and coordination of care with other providers in the pre and post-discharge periods (communication with the dialysis provider; medication reconciliation) have the potential to prevent hospital readmissions for ESRD dialysis patients. Preventing hospital readmissions is regarded as a shared responsibility that can be impacted by both dialysis providers and hospitals.

Several studies and commentaries strongly suggest pre- and post-discharge interventions within the purview of dialysis providers may reduce the risk of unplanned readmissions within the ESRD chronic dialysis population (Assimon, Wang, and Flythe 2018; Plantinga et al 2018; Flythe et al 2017, 2016; Chan et al 2017; Assimon and Flythe 2017; Plantinga and Jaar 2017). Plantinga et al (2018) found that interventions in the immediate post-discharge period were associated with reduced readmission risk among hemodialysis patients. They also suggest that post-discharge processes of care may help identify certain patients at higher risk for readmission, creating opportunities for dialysis providers to initiate interventions to reduce readmissions. Chan and colleagues (2009) found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission. Assessments included hemoglobin testing and modification of EPO dose; mineral and bone disease testing and modification of vitamin D; and, importantly, modification of dry weight after discharge. The risk of unplanned hospital readmission was reduced when these assessments were completed within the first seven days post-hospital discharge. In a commentary (Wish 2014) the Chan 2009 study and several others are cited as examples of the potential for care coordination to reduce readmissions among ESRD dialysis patients. The findings from Chan 2009 are further supported by results from a recent study (Lin et. al. CJASN, 2019) comparing principal diagnosis of index hospitalizations and their associated readmissions. Tables included in the paper's supplementary materials clearly demonstrate that a significant portion of readmission principal discharge diagnoses are for dialysis-related conditions. For example, regardless of the index hospitalization cause (i.e. infectious, endocrine, cardiovascular, GI, dermatologic, renal, etc), the top principal discharge diagnosis lists for related readmissions prominently included diagnoses typically associated with fluid overload and failure of fluid management in dialysis patients (fluid overload, hypertension, CHF, etc). These results support the early findings from Chan 2009, nearly a decade earlier, showing that adjustment of patient target weight in the early post-hospitalization discharge period (to adjust for the frequent weight loss and/or in-hospital re-assignment of a lower post-dialysis target weight) is a likely mechanism for a substantial minority of unplanned readmissions in the US chronic dialysis population.

Finally, findings from the first two performance years of the Center for Medicare and Medicaid Innovation's Comprehensive ESRD Care Initiative suggest care coordination may reduce readmission risk (The Lewin Group, 2019). The findings of this controlled study showed an overall decrease in the percentage of Medicare beneficiaries with at least one readmission, among those aligned to an ESRD Seamless Care Organization, relative to a matched comparison group of facilities

Studies in the non-dialysis setting have cited post-interventions or a combination of pre-and post-discharge interventions as drivers for reducing unplanned readmissions (Dunn 1994; Bostrom 1996; Dudas 2001; Azevedo 2002; Coleman 2004; Coleman 2006; Balaban 2008; Braun 2009; Naylor 1994; McDonald 2001; Creason 2001; Ahmed 2004; Anderson 2005; Jack 2009; Koehler 2009; Parry 2009). However, a recent study and related commentary challenge the reported magnitude of reductions in hospital-wide readmissions since 2010, as part of the publicly reported Hospital Wide Readmission (HWR) measure for the Hospital Readmission Reduction Program (HRRP) (Wadhera, Yeh, and Joynt-Maddox 2019; Ody et al 2019). They suggest the potential driver of these reductions is in part attributed to a change in diagnosis coding policy for inpatient claims that took effect in October 2012. While it is not yet settled whether the reductions were primarily or only nominally driven by the ability of hospitals to report more condition diagnoses, resulting in more robust comorbidity risk adjustment in the measure, the concern has generated attention about whether reported improvements in readmission rates is a result of the HWR and by extension better care delivery by hospitals. These concerns are not considered germane to drivers of readmission reduction based on the dialysis facility readmission measure. The SRR was implemented by CMS in 2015, after the 2012 coding changes took effect. Therefore trends in dialysis patient 30-day readmissions only reflect the period since the claims based diagnoses coding changes, and observed reductions since that time are not considered an artifact of the 2012 inpatient diagnosis coding changes.

Ahmed A, Thornton P, Perry GJ, Allman RM, DeLong JF. Impact of atrial fibrillation on mortality and readmission in older adults hospitalized with heart failure. Eur J Heart Fail. 2004;6(4):421–426.

Anderson MA, Clarke MM, Helms LB, Foreman MD. Hospital readmission from home health care before and after prospective payment. J Nurs Scholarsh. 2005;37(1):73–79.

Azevedo A, Pimenta J, Dias P, Bettencourt P, Ferreira A, Cerqueira-Gomes M. Effect of a heart failure clinic on survival and hospital readmission in patients discharged from acute hospital care. Eur J Heart Fail. 2002 Jun;4(3):353–359.

Balaban RB, Weissman JS, Samuel PA, Woolhandler S. Redefining and redesigning hospital discharge to enhance patient care: a randomized controlled study. J Gen Intern Med. 2008;23(8):1228–1233.

Bostrom J, Caldwell J, McGuire K, Everson D. Telephone follow-up after discharge from the hospital: Does it make a difference? Appl Nurs Res. 1996;9:47–52.

Braun E, Baidusi A, Alroy G, Azzam ZS. Telephone follow-up improves patients satisfaction following hospital discharge. Eur J Internal Med. 2009;20:221–225.

Chan K, Lazarus M, Wingard R, et al. "Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge." Kidney International (2009) 76:331-41.

Coleman E, Parry C, Chalmers S, et al. The care transitions intervention. Arch Internal Med. 2006;166:1822–1828.

Creason H. Congestive heart failure telemanagement clinic. Lippencotts Case Management: Managing the Process of Patient Care. 2001 Jul-Aug;6(4):146-56.

Dudas V, Bookwalter T, Kerr KM et al. The impact of follow-up telephone calls to patients after hospitalization. American Journal of Medicine. 2001; 111(9B):26S-30S

Dunn JM, Elliot TB, Lavy JA et al. Outpatient clinic review after arterial reconstruction: is it necessary? Annals of the Royal College of Surgeons of England. 1994 Sep;76(5):304-6.

Jack B, Chetty V, Anthony D, et al. "A reengineered hospital discharge program to decrease rehospitalizaton." Annals of Internal Medicine (2009) 150:178-88.

Koehler BE, Richter KM, Youngblood L et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. Journal of Hospital Medicine. 2009 Apr;4(4):211-8.

McDonald, MD. The hospitalist movement: wise or wishful thinking? Nurse management. 2001 Mar;32(3):30-1.

Naylor M, Brooten D, Jones R et al. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Annals of Internal Medicine. 1994 Jun 15;120(12):999-1006.

Parry C, Min SH, Chugh A et al. Further application of the care transitions intervention: results of a randomized controlled trial conducted in a fee-for-service setting. Home Health Care Services Quarterly. 2009;28(2-3):84-99.

United States Renal Data System. 2018 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018

1b.2. Provide performance scores on the measure as specified (current and over time) at the specified level of analysis. (*This is required for maintenance of endorsement*. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Unadjusted (raw) Readmission Rates:

2016: 0.265 2017: 0.264 2018: 0.263

2016: 6,442 facilities, SRR mean: 0.99, SD: 0.28, min: 0.00, max: 2.61, IQR: 0.33, deciles (10-90): 0.65, 0.78, 0.87, 0.93, 1.00, 1.06, 1.13, 1.20, 1.32

2017: 6,682 facilities, SRR mean: 1.00, SD: 0.28, min: 0.00, max: 2.47, IQR: 0.33, deciles (10-90): 0.66, 0.79, 0.84, 0.94, 1.00, 1.06, 1.13, 1.21, 1.32

2018: 6,937 facilities, SRR mean: 1.00, SD: 0.29, min: 0.00, max: 3.69, IQR: 0.34, deciles (10-90): 0.66, 0.78, 0.87, 0.94, 1.00, 1.06, 1.13, 1.21, 1.34

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

N/A

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (*This is* required for maintenance of endorsement. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Sex (Male used as ref. group):

2016: 0.03 estimate, 0.01 standard error, 0.0008 p-value 2017: 0.04 estimate, 0.01 standard error, <0.0001 p-value

2018: 0.04 estimate, 0.01 standard error, <0.0001 p-value

Race (White used as ref. group):

American Indian or Alaskan Native:

2016: 0.0009 estimate, 0.05 standard error, 0.9856 p-value

2017: -0.07 estimate, 0.05 standard error, 0.1076 p-value

2018: 0.03 estimate, 0.04 standard error, 0.5445 p-value

Asian:

2016: -0.05 estimate, 0.02 standard error, 0.0342 p-value 2017: -0.04 estimate, 0.02 standard error, 0.1105 p-value 2018: -0.08 estimate, 0.02 standard error, 0.0005 p-value

Black:

2016: -0.02 estimate, 0.01 standard error, 0.0912 p-value 2017: -0.03 estimate, 0.01 standard error, 0.0067 p-value 2018: -0.02 estimate, 0.01 standard error, 0.0796 p-value

Other race:

2016: -0.08 estimate, 0.07 standard error, 0.3108 p-value 2017: -0.05 estimate, 0.07 standard error, 0.4398 p-value 2018: -0.09 estimate, 0.07 standard error, 0.2045 p-value

Hispanic Ethnicity (Non-Hispanic used as ref. group): 2016: -0.03 estimate, 0.01 standard error, 0.0132 p-value 2017: -0.06 estimate, 0.01 standard error, <0.0001 p-value 2018: -0.04 estimate, 0.01 standard error, <0.0001 p-value

Medicare Dual Eligible (Non-Dual Eligible used as ref. group): 2016: 0.03 estimate, 0.01 standard error, 0.0001 p-value 2017: 0.04 estimate, 0.01 standard error, <0.0001 p-value 2018: 0.06 estimate, 0.01 standard error, <0.0001 p-value

Area Deprivation Index:

2016: 0.0003 estimate, 0.0003 standard error, 0.1903 p-value 2017: 0.0004 estimate, 0.0003 standard error, 0.1294 p-value 2018: 0.0004 estimate, 0.0003 standard error, 0.1749 p-value

The analysis results provided from above are from data year 2018 using a logistic regression model. Investigations of the SRR by population group identified some potential disparities. Female, Medicare dual eligible, and American Indian or Alaskan Native (compared to White) patients are more likely to experience a readmission within 4 to 30 days. On the other hand, compared to White patients, Asian, patients were less likely to experience a readmission. Finally, Black and patients of other races did not have significant differences compared to White patients nor did zip code Area Deprivation Index levels significantly predict readmission. The associations of these respective demographic and SES characteristics with readmission were stable over the time period examined.

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, <u>as specified</u>, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. *Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.*

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

De.5. Subject/Topic Area (check all the areas that apply): Renal, Renal : End Stage Renal Disease (ESRD)

De.6. Non-Condition Specific(*check all the areas that apply*): Care Coordination, Care Coordination : Readmissions, Care Coordination : Transitions of Care

De.7. Target Population Category (Check all the populations for which the measure is specified and tested if any): Populations at Risk

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

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

This is not an eMeasure Attachment:

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff) Attachment Attachment: 2496_Data_Dictionary_Code_Table.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available. No, this is not an instrument-based measure **Attachment**:

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available. Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2. Yes

S.3.2. For maintenance of endorsement, please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

1. In the currently endorsed SRR, select categories from the 2009 CMS Hierarchical Condition Categories (HCC) were used to identify patient prevalent comorbidities in Medicare outpatient, inpatient, hospice, skilled nursing, and home health claims occurring in the previous 365 days from the index discharge. These categories were then used as prevalent comorbidity indicators in the SRR model. Two changes to this process have been made: the use of AHRQ CCS diagnosis categories to identify patient prevalent comorbidities and the sole use of Medicare inpatient claims as a source of prevalent comorbidities.

CMS Hierarchical Condition Categories (HCC) were developed to pay Medicare Advantage Organizations differentially based on disease burden and demographics. Thus, ICD codes may not be grouped in clinically meaningful ways. In contrast, AHRQ CCS categories are designed to group ICD codes into clinically meaningful groups. Furthermore, other measures submitted for maintenance by UM-KECC are also proposing to use AHRQ CCS diagnosis categories.

The switch to using only Medicare inpatient claims to identify prevalent comorbidities is due to the lack of Medicare outpatient claims data for the growing Medicare Advantage (MA) patient population. By using the original set of Medicare claims datasets (inpatient, outpatient, hospice, skilled nursing, and home health), MA patient prevalent comorbidities would be systematically biased as they would only be populated by Medicare inpatient claims compared to non-MA patient prevalent comorbidities that would be populated by the aforementioned set of Medicare claim sources. In addition, we have added a variable to the model that indicates whether or not the patient was a Medicare Advantage patient at the time of index discharge.

2. Identification of rehabilitation inpatient stays has been augmented. With the introduction of ICD10 codes, the Agency for Healthcare Research and Quality's Clinical Classification Software (AHRQ CCS) diagnosis category 254 "Rehabilitation care; fitting of prostheses; and adjustment of devices" no longer adequately identified rehabilitation inpatient stays. In addition to the use of AHRQ CCS diagnosis category 254, the inpatient stay hospital CCN is now examined to determine if the stay occurred at a rehabilitation facility or a rehabilitation unit within a hospital. Specifically if the last 4 digits of the 6 digit CCN fall in the range between 3025 and 3099 or include the character value of "R: Critical Access Hospital, Rehabilitation Unit", "T: Rehabilitation Unit", or "Y: Rehabilitation Hospital". Finally, rehabilitation units within hospitals in the state of Maryland do not receive their own CCN. We seek to further identify these rehabilitation inpatient stays occurring at rehabilitation units within hospitals in the state of Maryland by

flagging those inpatient stays that use the revenue center codes "0024", "0018", "0128", "0138", "0148", and "0158" as rehabilitation inpatient stays.

3. In addition to removing those index discharges with any type of inpatient admission within the first 0 to 3 days following the index discharge, those index discharges that are associated with a death, transplant, or a change of status to non-dialysis within the first 0 to 3 days have also been removed. This change improves the SRR's measurement of the quality of transitional care 4 to 30 days after an inpatient visit by removing those cases where the transitional care route was impeded by an event.

4. A patient's time spent in the nursing home in the previous 365 days may play a role in readmission rates following an inpatient discharge. UM-KECC has leveraged information from the Medicare Minimum Dataset (MDS) regarding a patient's time spent in a nursing home in the 365 days prior to the index discharge to create three distinct groups to use in the SRR model. The three groups are those patients who have spent 0, 1-89 (short term), or 90 or more (long term) days in the nursing home in the previous 365 days from the index discharge.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.

<u>IF an OUTCOME MEASURE</u>, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

Each facility's observed number of hospital discharges that are followed by an unplanned hospital readmission within 4-30 days of discharge.

S.5. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

<u>IF an OUTCOME MEASURE</u>, describe how the observed outcome is identified/counted. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

The numerator for a given facility is the total number of index hospital discharges that are followed by unplanned readmissions within 4-30 days of discharge and that are not preceded by a "planned" readmission or other competing event that also occurred within 4-30 days of discharge. Terms in this definition are described below.

A readmission is considered "planned" under two scenarios as outlined more completely in [1]:

i). The patient undergoes a procedure that is always considered planned (e.g., kidney transplant) or has a primary diagnosis that always indicates the hospitalization is planned (e.g., maintenance chemotherapy).

ii). The patient undergoes a procedure that MAY be considered planned if it is not accompanied by an acute diagnosis. For example, a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of diabetes would be considered planned, whereas a hospitalization involving a heart valve procedure accompanied by a primary diagnosis of acute myocardial infarction (AMI) would be considered unplanned.

1. Centers for Medicare and Medicaid Services. 2018 All-Cause Hospital Wide Measure Updates and Specifications Report Hospital-Level 30-Day Risk-Standardized Readmission Measure – Version 7.0. https://www.qualitynet.org/files/5d0d375a764be766b010141f?filename=2018_Rdmsn_Updates%26Specs_Rpts.zip

Other competing events include admissions to rehabilitation or psychiatric hospitals, death, transplant, loss to follow up, withdrawal from dialysis, and recovery of renal function.

S.6. Denominator Statement (Brief, narrative description of the target population being measured)

The denominator for a given facility is the expected number of the observed index hospital discharges that result in an unplanned readmission in days 4-30 and that are not preceded by an unplanned or competing event. The expectation accounts for patient-level characteristics, including measures of patient comorbidities, and the discharging hospital, and is based on estimated readmission rates for an overall population norm that corresponds to an "average" facility.

S.7. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of

individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

<u>IF an OUTCOME MEASURE</u>, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

We use Medicare inpatient hospital claims to identify acute hospital discharges. All Medicare covered live inpatient discharges of ESRD dialysis patients in a calendar year are considered eligible for this measure.

An index hospital discharge is a discharge from an acute care hospital that is not followed by a readmission whether planned or unplanned or by any competing event in the first three days following discharge.

Index discharges are attributed to the facility of record on the day of discharge for the patient. That is, if the patient transfers dialysis facilities at the time of hospital discharge, it is the new facility that is assigned the index discharge.

Expected Calculation: We calculate each dialysis facility's expected number of index hospital discharges during the one year period that are followed by an unplanned readmission within 4-30 days of the discharge. The expected number is calculated by fitting a model with random effects for discharging hospitals, fixed effects for facilities, and regression adjustments for a set of patient-level characteristics. We compute the expectation for the given facility assuming readmisson rates corresponding to an "average" facility with the same patient characteristics and same discharging hospitals as this facility. Model details are provided in the testing form.

S.8. Denominator Exclusions (Brief narrative description of exclusions from the target population) Index Discharge Exclusions:

A live inpatient hospital discharge is excluded if any of the following hold:

- Associated with a stay of 365 days or longer
- It is against medical advice
- It Includes a primary diagnosis of cancer, mental health or rehabilitation
- It Includes revenue center codes indicating rehabilitation
- It occurs after a patient's 12th hospital discharge in the calendar year
- It is from a PPS-exempt cancer hospital

• It is followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit) or any other competing event (see S.5).

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

• Discharged against medical advice: We determine discharge status from the inpatient claim.

• Certain diagnoses: The primary diagnosis at discharge is available on the inpatient claim; we group these diagnoses into more general categories using AHRQ's Clinical Classification Software (CCS; see

http://www.hcup-us.ahrq.gov/toolssoftware/ccs/ccs.jsp for descriptions of each CCS). The excluded CCSs are shown below.

o Cancer: 42, 19, 45, 44, 17, 38, 39, 14, 40, 35, 16, 13, 29, 15, 18, 12, 11, 27, 33, 32, 24, 43, 25, 36, 21, 41, 20, 23, 26, 28, 34, 37, 22, 31, 30

o Psychiatric: 657, 659, 651, 670, 654, 650, 658, 652, 656, 655, 662

o Rehab for prosthesis: 254

o Presence of one or more of the following revenue center codes: 0024, 0118, 0128, 0138, 0148, 0158

• Number of admissions: We remove any records for a patient after his/her 12th discharge in the calendar year.

• PPS-exempt cancer hospitals: The following hospitals are listed as PPS-exempt cancer hospitals in the Federal Register (http://www.gpo.gov/fdsys/pkg/FR-2011-07-18/html/2011-16949.htm): 050146, 050660, 100079, 100271, 220162, 330154, 330354, 360242, 390196, 450076, 500138

• Any index discharge with an inpatient readmission of any type, a death, a transplant, loss to follow-up, withdrawal from dialysis, or recovery of renal function occurring within the first 0-3 days following the index discharge.

S.10. Stratification Information (Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.) N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment) Statistical risk model If other:

S.12. Type of score: Ratio If other:

S.13. Interpretation of Score (*Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score*) Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.) See flowchart in appendix.

S.15. Sampling (*If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.*)

<u>IF an instrument-based</u> performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A

S.16. Survey/Patient-reported data (If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.)

Specify calculation of response rates to be reported with performance measure results. $\ensuremath{\mathsf{N/A}}$

S.17. Data Source (Check ONLY the sources for which the measure is SPECIFIED AND TESTED). If other, please describe in S.18. Claims, Registry Data

S.18. Data Source or Collection Instrument (Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.) <u>IF instrument-based</u>, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Data are derived from an extensive national ESRD patient database, which is primarily based on 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 and patient tracking data), the Medicare Enrollment Database (EDB), and Medicare claims data. In addition the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC).

The database is comprehensive for Medicare patients not enrolled in Medicare Advantage. Medicare Advantage patients are included in all sources but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage.

Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs).

S.19. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1) No data collection instrument provided

S.20. Level of Analysis (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED) Facility **S.21. Care Setting** (Check ONLY the settings for which the measure is SPECIFIED AND TESTED) Other

If other: Dialysis Facility

S.22. <u>COMPOSITE Performance Measure</u> - Additional Specifications (Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.) N/A

2. Validity – See attached Measure Testing Submission Form

2496_NQF_testing.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing. Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing. Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions. Yes - Updated information is included

Measure Testing (subcriteria 2a2, 2b1-2b6)

NATIONAL QUALITY FORUM—Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (if previously endorsed): 2496

Measure Title: Standardized Readmission Ratio for dialysis facilities

Date of Submission: 1/5/2020

Type of Measure:

Outcome (including PRO-PM)	Composite – <i>STOP – use composite</i>	
	testing form	
Intermediate Clinical Outcome	□ Cost/resource	
Process (including Appropriate Use)	Efficiency	
Structure		

Instructions

- Measures must be tested for all the data sources and levels of analyses that are specified. If there is more than one set of data specifications or more than one level of analysis, contact NQF staff about how to present all the testing information in one form.
- For <u>all</u> measures, sections 1, 2a2, 2b1, 2b2, and 2b4 must be completed.
- For outcome and resource use measures, section 2b3 also must be completed.

- If specified for <u>multiple data sources/sets of specificaitons</u> (e.g., claims and EHRs), section **2b5** also must be completed.
- Respond to <u>all</u> questions as instructed with answers immediately following the question. All information on testing to demonstrate meeting the subcriteria for reliability (2a2) and validity (2b1-2b6) must be in this form. An appendix for *supplemental* materials may be submitted, but there is no guarantee it will be reviewed.
- If you are unable to check a box, please highlight or shade the box for your response.
- Maximum of 25 pages (*incuding questions/instructions;* minimum font size 11 pt; do not change margins). **Contact** NQF staff if more pages are needed.
- Contact NQF staff regarding questions. Check for resources at <u>Submitting Standards webpage</u>.
- For information on the most updated guidance on how to address social risk factors variables and testing in this form refer to the release notes for version 7.1 of the Measure Testing Attachment.

Note: The information provided in this form is intended to aid the Standing Committee and other stakeholders in understanding to what degree the testing results for this measure meet NQF's evaluation criteria for testing.

2a2. Reliability testing ¹⁰ demonstrates the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise. For instrument-based measures (including PRO-PMs) and composite performance measures, reliability should be demonstrated for the computed performance score.

2b1. Validity testing ¹¹ demonstrates that the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For **instrument-based measures** (including PRO-PMs) and composite performance measures, validity should be demonstrated for the computed performance score.

2b2. Exclusions are supported by the clinical evidence and are of sufficient frequency to warrant inclusion in the specifications of the measure; ¹²

AND

If patient preference (e.g., informed decisionmaking) is a basis for exclusion, there must be evidence that the exclusion impacts performance on the measure; in such cases, the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately). ¹³

2b3. For outcome measures and other measures when indicated (e.g., resource use):

• an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified; is based on patient factors (including clinical and social risk factors) that influence the measured outcome and are present at start of care; ^{14,15} and has demonstrated adequate discrimination and calibration

OR

• rationale/data support no risk adjustment/ stratification.

2b4. Data analysis of computed measure scores demonstrates that methods for scoring and analysis of the specified measure allow for **identification of statistically significant and practically/clinically meaningful** ¹⁶ differences in performance;

OR

there is evidence of overall less-than-optimal performance.

2b5. If multiple data sources/methods are specified, there is demonstration they produce comparable results.

2b6. Analyses identify the extent and distribution of **missing data** (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias.

Notes

10. Reliability testing applies to both the data elements and computed measure score. Examples of reliability testing for data elements include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing of the measure score addresses precision of measurement (e.g., signal-to-noise).

11. Validity testing applies to both the data elements and computed measure score. Validity testing of data elements typically analyzes agreement with another authoritative source of the same information. Examples of validity testing of the measure score include, but are not limited to: testing hypotheses that the measures scores indicate quality of care, e.g., measure scores are different for groups known to have differences in quality assessed by another valid quality measure or method; correlation of measure scores with another valid indicator of quality for the specific topic; or relationship to conceptually related measures (e.g., scores on process measures to scores on outcome measures). Face validity of the measure score as a quality indicator may be adequate if accomplished through a systematic and transparent process, by identified experts, and explicitly addresses whether performance scores resulting from the measure as specified can be used to distinguish good from poor quality. The degree of consensus and any areas of disagreement must be provided/discussed.

12. Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.

13. Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

14. Risk factors that influence outcomes should not be specified as exclusions.

15. With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74 percent v. 75 percent) is clinically meaningful; or whether a statistically significant difference of significant difference of care (e.g., \$5,000 v. \$5,025) is practically meaningful. Measures with overall less-than-optimal performance may not demonstrate much variability across providers.

1. DATA/SAMPLE USED FOR <u>ALL</u> TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. <u>If there are differences by aspect of testing</u>, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for <u>all</u> the sources of data specified and intended for measure implementation. **If different data sources are used for the numerator and denominator. indicate N Inumerator D Idenominator after the checkbox.**)

Measure Specified to Use Data From:	Measure Tested with Data From:		
(must be consistent with data sources entered in S.17)			
□ abstracted from paper record	□ abstracted from paper record		
🛛 claims	🛛 claims		
🛛 registry	🖾 registry		
□ abstracted from electronic health record	□ abstracted from electronic health record		
eMeasure (HQMF) implemented in EHRs	eMeasure (HQMF) implemented in EHRs		
□ other: Click here to describe	□ other: Click here to describe		

1.2. If an existing dataset was used, identify the specific dataset (the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

These data are part of an extensive and comprehensive national ESRD patient database, derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS

Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File.

2019 Submission

Data are derived from an extensive national ESRD patient database, which is primarily based on 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 and patient tracking data), the Medicare Enrollment Database (EDB), and Medicare claims data. In addition the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Compare (DFC).

The database is comprehensive for Medicare patients not enrolled in Medicare Advantage. Medicare Advantage patients are included in all sources but their Medicare payment records are limited to inpatient claims. Non-Medicare patients are included in all sources except for the Medicare payment records. Tracking by dialysis provider and treatment modality is available for all patients including those with only partial or no Medicare coverage.

Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs).

1.3. What are the dates of the data used in testing?

1/1/2009-12/31/2009 for index discharges and 1/1/2009-1/30/2010 for readmissions

2019 Submission

1/1/2018 – 12/31/2018 for index discharges and 1/1/2018 – 1/30/2019 for readmissions

1.4. What levels of analysis were tested? (testing must be provided for <u>all</u> the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan)

Measure Specified to Measure Performance of: (must be consistent with levels entered in item S.20)	Measure Tested at Level of:
individual clinician	individual clinician
□ group/practice	□ group/practice
hospital/facility/agency	hospital/facility/agency
🗆 health plan	health plan
□ other: Click here to describe	□ other: Click here to describe

1.5. How many and which <u>measured entities</u> were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample)

We included all Medicare-certified facilities treating Medicare dialysis patients (n = 6,127) in 2009. Median facility size was 83 patients. Most facilities were free-standing (80.4%) and located in non-rural areas (79.4%).

2019 Submission

There were n=6,937 (with an average of 55.1 patient-years-at-risk) Medicare-certified dialysis facilities with at least 11 eligible index discharges in 2018 included in the testing and analysis*.

* In previous submission, facility size was measured by the number of distinct patients treated by the facility during the year of interest. For the 2019 submission, facility size is measured by patient-years-at-risk in 2018.

1.6. How many and which <u>patients</u> were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample)

After applying the exclusion criteria, these data represent all Medicare-paid hospital discharges for Medicare dialysis patients (n = 234,717) during 2009. Patients were mostly white (59.4%) and male (52.9%); the most common types of diagnoses were Complications of Device, Implant or Graft (CCS 237); Congestive Heart Failure, Nonhypertensive (CCS 108); and Hypertension with Complications and Secondary Hypertension (CCS 99).

2019 Submission

After applying exclusion criteria, these data represent all Medicare hospital discharges (n=541, 769) for Medicare dialysis patients (n = 257,860) during 2018. Patients were mostly white (61.1%) and male (54.5%); the most common types of AHRQ CCS diagnosis categories related to the index discharge primary diagnosis were: Hypertension with complications and secondary hypertension (CCS 99), Complications of device; implant or graft (CCS 237), and Septicemia (CCS 2).

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

Not applicable.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

2019 Submission

Patient level:

- Employment status 6 months prior to ESRD
- Sex (add note already in the model)
- Race
- Ethnicity
- Medicare Dual Eligible
- ZIP code level Area Deprivation Index (ADI) from Census data (2009-2013). Based on patient zipcode.

2a2. RELIABILITY TESTING

<u>Note</u>: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.

2a2.1. What level of reliability testing was conducted? (may be one or both levels)

Critical data elements used in the measure (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

Performance measure score (e.g., *signal-to-noise analysis*)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (describe the steps—do not just name a method; what type of error does it test; what statistical analysis was used)

If the measure were a simple average across individuals in the facility, the NQF-recommended approach for determining measure reliability would be a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined.1 The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance. The SRR, however, is not a simple average and we instead estimate the IUR using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA.

Suppose that there are *N* facilities with at least 11 discharges in the year. Let $T_1,...,T_N$ be the SRR for these facilities. Within each facility, select at random and with replacement B = 100 bootstrap samples. That is, if the *i*th facility has n_i subjects, randomly draw with replacement n_i subjects from those in the same facility, find their corresponding SRR_i and repeat the process 100 times. Thus, for the *i*th facility, we have bootstrapped SRRs of $T_{i1...,}^{*}$ the sample variance of this bootstrap sample. From this it can be seen that

$$s_{t,w}^2 = \frac{\sum_{i=1}^{N} [(n_i - 1)S_i^{*2}]}{\sum_{i=1}^{N} (n_i - 1)}$$

is a bootstrap estimate of the within-facility variance in the SRR, namely $\sigma_{t,w'}^2$. Calling on formulas from the one way analysis of variance, an estimate of the overall variance of T_i is

$$s_t^2 = \frac{1}{n'(N-1)} \sum_{i=1}^N n_i (T_i - \overline{T})^2$$

where

$$\bar{T} = \sum n_i T_i / \sum n_i$$

is the weighted mean of the observed SRR and

$$n' = \frac{1}{N-1} \left(\sum n_i - \sum n_i^2 / \sum n_i \right)$$

is approximately the average facility size (number of patients per facility). Note that s_t^2 is an estimate of $\sigma_b^2 + \sigma_{t,w}^2$ where σ_b^2 is the between-facility variance, the true signal reflecting the differences across facilities. Thus, the IUR, which is defined by

$$IUR = \frac{\sigma_b^2}{\sigma_b^2 + \sigma_{t,w}^2}$$

can be estimated with $(s_t^2 - s_{t,w}^2)/s_t^2$

2019 Submission

The methodology described above [3] has been applied to the IUR calculation for this submission. To assess more directly the value of SRR in identifying facilities with extreme outcomes, we also computed an additional metric of reliability, termed the profile IUR (PIUR) [1]. The PIUR was developed since the IUR can be quite small if there are many facilities which have outcomes similar to the national norm, even though the measure is still very useful to identify facilities with extreme outcomes [2]. The PIUR is based on the measure's ability to consistently flag the same facilities. We proceed in two steps: first, we evaluate the ability of a measure to consistently profile facilities with extreme outcomes; second, we use the IUR to calibrate PIUR. Specifically, we consider a sample-splitting approach: within each facility randomly split patients into two equal-sized subgroups. For a given threshold (e.g. p-value or z-score in a hypothesis testing procedure), determine whether each facility is identified as extreme based on the first and the second subgroups. Repeat this process 100 times to estimate the probability that, given a facility is classified as extreme based on the first subgroup, it is also classified as extreme based on the second subgroup. This empirical reflagging rate is calibrated to give the PIUR by determining the IUR value that would yield this reflagging rate in the absence of outliers. The PIUR measures reliability in terms of the probability of reflagging rates but is on the same scale as IUR. The PIUR is

substantially larger than the IUR when the data include many outliers or extreme values that are not captured in the IUR itself.

- 1. He K, Dahlerus C, Xia L, Li Y, Kalbfleisch JD. The profile inter-unit reliability. Biometrics. 2019 Oct 23. doi: 10.1111/biom.13167. [Epub ahead of print]
- 2. Kalbfleisch JD, He K, Xia L, Li Y. Does the inter-unit reliability (IUR) measure reliability?, Health Services and Outcomes Research Methodology, 2018 Sept. 18(3), 215-225. Doi: 10.1007/s10742-018-0185-4.
- 3. He K, Kalbfleisch JD, Yang Y, Fei Z. Inter-unit reliability for nonlinear models. Stat Med. 2019 Feb 28;38(5):844-854. doi: 10.1002/sim.8005. Epub 2018 Oct 18.

2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis)

Overall, we found that IUR = .55 (F statistic = 2.24), which indicates that about one half of the variation in the SRR can be attributed to the between-facility differences and about half to within-facility variation.

Facility Size (No. of	No. of Facilities	IUR	F-statistic
Patients)			
Small (<=70)	1732	.46	1.85
Medium (71–121)	1784	.54	2.18
Large (>121)	1757	.61	2.53

Table 1. Inter-unit Reliability Measure of SRR, by Facility Size (2009)

2019 Submission

Overall, we found that IUR = 0.35 The PIUR is 0.61. As noted above, the PIUR measures reliability in terms of reflagging rates but is placed on the same scale as IUR. The higher PIUR compared to the IUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. If there are no outliers, one should expect the PIUR to be similar to the IUR; but in cases where there are outlier providers, even measures with a low IUR can have relatively high PIUR and can be very useful for identifying extreme providers.

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.e., what do the results mean and what are the norms for the test conducted?)

This value of IUR indicates a moderate degree of reliability. When stratified by facility size, we find that, as expected, larger facilities have greater IUR.

2019 Submission

The value obtained for the IUR is low to moderate in size. The PIUR is larger and demonstrates that the SRR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.

2b1. VALIDITY TESTING

- **2b1.1. What level of validity testing was conducted**? (may be one or both levels)
- Critical data elements (data element validity must address ALL critical data elements)
- Performance measure score
 - ⊠ Empirical validity testing

□ Systematic assessment of face validity of <u>performance measure score</u> as an indicator of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)

Validation of critical data elements: The critical data elements for this measure (hospital admission and discharge dates for Medicare dialysis patients) come from Medicare claims data. The validity of these data is ensured by the oversight of the Medicare program in the payment process.

Validation of performance measure score: We assessed the validity of the measure through various comparisons of this measure with other quality measures in use, and in May 2012, presented a preliminary version of the SRR to a CMS Technical Expert Panel (TEP) for clinical validity. As hospitalization is a major cost factor in the management of ESRD patients, there is a strong case for face validity of the SRR measure. We used Pearson correlation coefficients to examine the relationship between the SRR and other facility-level practice patterns.

2019 Submission

Validation of performance measure score: We assessed the validity of the measure through comparisons of this measure with other quality measures in use, using Pearson correlation coefficients to examine the relationship between the SRR and other facility-level quality measures.

- Standardized Hospitalization Ratio (SHR)- We expect a fairly strong positive association with SHR since readmissions are also hospital admissions. Additionally, both hospitalization and readmission are a reflection of hospital utilization and increased comorbidity burden.
- Standardized Mortality Ratio (SMR)- We expect a positive association with SMR. Patients who require acute inpatient medical care represent an at-risk population for mortality since they likely have greater acute medical needs or complications from chronic comorbid conditions that put them at higher risk for death. Higher SMR will be positively associated with SRR.
- Vascular Access: Long-term catheter rate (catheter in use >=3 continuous months) We expect a
 positive association between long-term catheter rate and SRR. Long-term catheters put patients at
 increased risk for infection and other complications. Additionally, a high long-term catheter rate also
 indicates a higher patient comorbidity burden at the facility level such that sicker patients who have a
 long-term catheter may also be more likely to be hospitalized and re-admitted after initial
 hospitalization. Higher long-term catheter rates will be positively associated with SRR.

 Vascular Access: Standardized Fistula Rate (SFR)– We expect a negative association between SFR and SRR. Successfully creating an AVF is generally seen as representing a robust process to coordinate care outside of the dialysis facility, and potentially reduces the likelihood of adverse events, like infection that can increase the risk of patient hospitalization and hospital readmission. Higher rates of the facility level SFR will be negatively associated with re-hospitalization as measured by SRR.

In addition, in May 2012, we presented a preliminary version of the SRR to a CMS Technical Expert Panel (TEP) for clinical validity. As hospitalization is a major cost factor in the management of ESRD patients, there is a strong case for face validity of the SRR measure.

2b1.3. What were the statistical results from validity testing? (*e.g., correlation; t-test*)

The measure is positively correlated with the one-year Standardized Hospitalization Ratio for Admissions (r = .53, p < .0001), the one-year Standardized Mortality Ratio (r = .19, p < .0001), and catheter use (r = .11, p < .0001). The SRR is negatively correlated with the percentage of patients having a Urea Reduction Ratio (URR) of at least 65% (r = .05, p = .001) and using a fistula (r = .09, p < .0001).

2019 Submission

The measure is positively correlated with the one-year Standardized Hospitalization Ratio for Admissions (r = 0.39, p < 0.0001), the Standardized Mortality Ratio (r = 0.10, p < 0.0001), and long term catheter use (r = 0.04, p = 0.0006). The SRR is negatively correlated with the rate of patients using a fistula (r = -0.06, p < 0.0001).

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.e., what do the results mean and what are the norms for the test conducted?)

The SRR is a measure of hospital use, comprising many causes of hospitalization. The TEP considered devising cause-specific SRRs but recommended the use of overall SRR measures due to various reasons, including the lack of clear consensus on which causes are modifiable by the dialysis facility and concerns about gaming the system if certain conditions are identified.

The face validity of the SRR measure is also supported by its association with other known quality measures, which include both dialysis facility outcomes and practices. Higher values of SRR are associated with higher rates of hospitalization and mortality. The SRR is also correlated with other quality measures (listed above), although the correlations are small.

In general terms, many TEP members agreed with the rationale for pursuing a readmission measure in the context of dialysis facilities, and that such a measure could help to promote shared accountability and continuity of care as dialysis patients are discharged from acute care hospitals. There were, however, two general points regarding validity that were raised and emphasized by TEP members in discussion, both at the in-person meeting and subsequently. First, several TEP members felt that it was important that the measure be adjusted for physician(s) also providing care for the patient. Second, some TEP members felt that the denominator based on the number of discharges was inappropriate and that the measure should make reference to the total number of patients under care at the facility. For the former point, it is CMS' view that dialysis facilities should be encouraged to coordinate with the nephrologists and other physicians with whom they work to reduce readmissions. We note that it is difficult to determine a unique physician associated with a discharge that could be used for adjustment, and in many cases, patients are being attended to by several physicians. It was also noted that adjustment for physician, even if possible, would mean that this measure did not harmonize in an important way with other ESRD (and general health care) measures approved by NQF and in use. It was therefore decided not to attempt any adjustment of this sort at the present time. The latter concern recognizes difficulties that arise with a random denominator. For example, a facility with a very low overall hospital utilization may, nonetheless have a high rate of readmissions. The interpretation and use of

the readmission measure on its own could therefore be misleading. This issue is also discussed in the material on pairing of measures (see De.4 in the Readmission Measure Specifications), where it is noted that the Standardized Hospitalization Ratio (SHR) and the SRR should be considered together. The SHR measure appropriately reflects the level of hospital usage among patients treated by the facility with the number of patients at the facility as the reference. The SRR, on the other hand, is looking specifically at the readmission process and provides additional insight into facility outcomes, an insight that might often help to promote shared accountability between hospitals and dialysis facilities. Furthermore the empirical correlation between SHR and SRR is about 0.5, reflecting that both measures are somewhat related but not to the extent of redundancy.

2019 Submission

The SRR is a measure of hospital use, comprising many causes of hospitalization. The TEP considered devising cause-specific SRRs but recommended the use of overall SRR measures due to various reasons, including the lack of clear consensus on which causes are modifiable by the dialysis facility and concerns about gaming the system if certain conditions are identified.

The validity of the SRR measure is also supported by its association with other known quality measures, which include both dialysis facility outcomes and practices. Higher values of SRR are associated with higher rates of hospitalization and mortality. The SRR is also correlated with other quality measures (listed above), although the correlations are small. The interpretation of the face validity garnered from the 2012 TEP described in the previous submission (above) carries forward to this submission.

2b2. EXCLUSIONS ANALYSIS

NA
no exclusions
- skip to section
2b3

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps*—*do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

In the process of developing the measure of 30-day unplanned readmissions in dialysis facilities, we exclude planned readmissions from the numerator (n = 49,639). For details on how we determined a readmission's status as planned, please see the Appendix.

We further exclude the following hospital discharges from the denominator:

- 1. Not a live discharge
- 2. Result in a patient dying within 30 days with no readmission
- 3. Are against medical advice
- 4. Include a primary diagnosis for cancer, mental health or rehabilitation
- 5. Are from a PPS-exempt cancer hospital
- 6. Result in a transfer to another hospital on the same day
- 7. Occur after a patient's 12th admission in the calendar year

The numerator exclusion and first six denominator exclusions are aligned with CMS' Hospital-Wide All-Cause readmission measure. We additionally excluded discharge records following a patient's 12th admission in response to concerns from some members of the TEP held in May 2012 for this measure. Specifically, it was felt that frequently hospitalized patients would unfairly penalize smaller facilities by inflating their facility's SRR. This concern is relevant in the context of the measure's potential applications, which are to identify poorperforming facilities for quality improvement purposes. In the context of dialysis facilities, 2.8% of discharges were followed by a death within 30 days with no readmission (corresponding to exclusion #2 above). This measure concentrates on readmissions, but a complementary measure reflecting mortality within 30 days of discharge might be considered.

In addition, the first and sixth exclusion criteria cannot result in a readmission and so are not relevant to a readmission statistic.

We determined the cut point (cap) for admissions by examining the distribution of the number of readmissions per patient. We compared SRRs with and without the admission cap to determine the extent to which the measure changed with the exclusion.

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In the process of developing the measure of 30-day unplanned readmissions in dialysis facilities, we exclude planned readmissions from the numerator (n = 12,523). For details on how we determined a readmission's status as planned, please see the Appendix.

We further exclude the following hospital discharges from the denominator using the below criteria:

- 1. Associated with a stay of 365 days or longer
- 2. Are against medical advice
- 3. Include a primary diagnosis of cancer, mental health or rehabilitation
- 4. Include revenue center codes indicating rehabilitation
- 5. Occur after a patient's 12th hospital discharge in the calendar year
- 6. Are from a PPS-exempt cancer hospital
- 7. Are followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit), or any other competing event*

* Other competing events include admissions to rehabilitation or psychiatric hospitals, death, transplant, loss to follow up, withdrawal or recovery

The numerator exclusion and first five denominator exclusions are aligned with CMS' Hospital-Wide All-Cause readmission measure. We additionally excluded discharge records following a patient's 12th discharge in response to concerns from some members of the TEP held in May 2012 for this measure. Specifically, it was felt that frequently hospitalized patients would unfairly penalize smaller facilities by inflating their facility's SRR. This concern is relevant in the context of the measure's potential applications, which are to identify poorperforming facilities for quality improvement purposes. Including exclusion 7 improves the SRR's measurement of the quality of transitional care 4 to 30 days after an inpatient visit by removing those cases where the transitional care route was impeded by an event. We compared SRRs with and without exclusion 7 to determine the extent to which the measure changed with the exclusion.

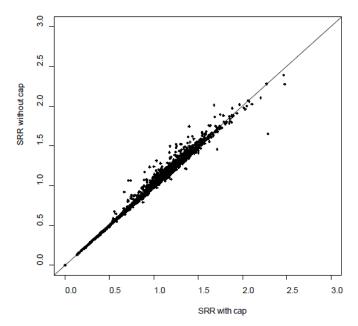
2b2.2. What were the statistical results from testing exclusions? (*include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores*)

The number and percentage of excluded discharges are as follows:

- 1. Not a live discharge (*n* = 31,593; 4.4%)
- 2. Result in a patient dying within 30 days with no readmission (n = 20,499; 2.8%)
- 3. Are against medical advice (*n* = 9,728; 1.3%)
- 4. Include a primary diagnosis for cancer, mental health or rehabilitation (*n* = 21,413; 3.0%)
- 5. Are from a PPS-exempt cancer hospital (*n* = 229; 0.03%)
- 6. Result in a transfer to another hospital on the same day (n = 21,818; 3.0%)
- 7. Occur after a patient's 12th admission in the calendar year (n = 5,155; 0.7%)

The Hospital-Wide All-Cause Readmission measure was a starting point for this measure and specified the first six exclusions. Regarding the admission-cap exclusion, we found that less than 1% of discharges were excluded based on this cap (0.5% of patients had more than 12 admissions in the year). As shown in Figure 1, we compared each facility's SRR with and without discharges following a patient's 12^{th} admission in the year and found the two measures to be highly correlated (overall Pearson correlation coefficient [r] = 0.99).







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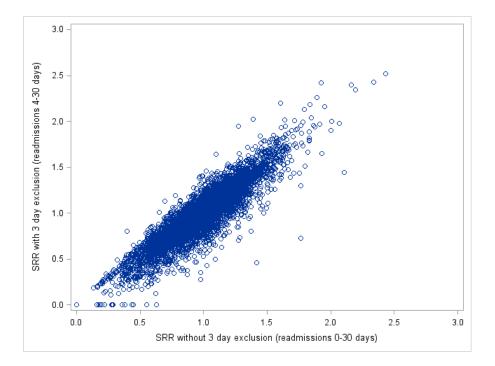
The number and percentage of excluded discharges are as follows:

- 1. Associated with a stay of 365 days or longer (n=54, 0.01%)
- 2. Are against medical advice (n=13,391, 1.9%)
- 3. Include a primary diagnosis of cancer, mental health or rehabilitation or a revenue center code indicating rehabilitation (n=10,051, 1.4%)
- 4. Occur after a patient's 12th hospital discharge in the calendar year (n=5,975, 0.9%)
- 5. Are from a PPS-exempt cancer hospital (n=964, 0.1%)
- 6. Are followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit), or any other competing event* (n=85,831, 12.2%)

* Other competing events include admissions to rehabilitation or psychiatric hospitals, death, transplant, loss to follow up, withdrawal or recovery.

The Hospital-Wide All-Cause Readmission measure was a starting point for this measure and specified the first five exclusions. Regarding the admission-cap exclusion, we found that 0.9% of discharges were excluded based on this cap (0.5% of patients had more than 12 admissions in the year). Given that exclusion 6 (a hospitalization, death, transplant, LTFU, withdrawal, or recovery in 3 days) is responsible for the majority of exclusions, we compared each facility's SRR with and without exclusion 6 (Exlcusion 6 was added to the measure during the previous NQF review process). In our removal exclusion 6, we allowed readmissions to occur in the 0 to 30 day period following an index discharge. We found the two measure approaches to be highly correlated (overall Pearson correlation coefficient r = 0.90). But, from the scatter plot in Figure 1, one can see that a facilities with an SHR of approximately 1.20 without the three day exclusion have SHRs that vary substantially.

Figure 1. Correlation between SRR with exclusion 6 and without exclusion 6 (2018).



2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e.*, the value outweighs the burden of increased data collection and analysis. <u>Note</u>: *If patient preference is an exclusion*, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion)

Based on the findings presented in Figure 1, we concluded that incorporating this exclusion—which has face validity and meets the intention of the TEP—is appropriate and supported by the high degree of correlation between the measure with and without this exclusion applied.

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This exclusion recognizes that facilities need some time to make arrangements for a discharged patient. As Figure 1 indicates, the exclusion does change the SRR substantially for some facilities due to the elimination of early readmissions, but these exclusions have been viewed as appropriate given the issues associated with transferring patient support at discharge.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section <u>2b4</u>.

2b3.1. What method of controlling for differences in case mix is used?

□ No risk adjustment or stratification

- Statistical risk model with Categories of Categories of risk factors
- Stratification by Click here to enter number of categories risk categories
- □ Other, Click here to enter description

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

To estimate the probability of 30-day unplanned readmission, we use a two-stage model, the first of which is a double random-effects logistic regression model. In this stage of the model, both dialysis facilities and hospitals are represented as random effects, and regression adjustments are made for a set of patient-level

characteristics. From this model, we obtain the estimated standard deviation of the random effects of hospitals (Diggle, et. al., 2002).

The second stage of the model is a mixed-effects logistic regression model, in which dialysis facilities are modeled as fixed effects and hospitals are modeled as random effects, with the standard deviation specified as equal to its estimates from the first model. The expected number of readmissions for each facility is estimated as the summation of the probabilities of readmission of all patients in this facility and assuming the national norm (i.e., the median) for facility effect. This model accounts for a given facility's case mix using the same set of patient-level characteristics as those in the first model.

The equations used in the measure calculation are as follows:

• To estimate the probability of 30-day unplanned readmission, we use a two-stage approach. The main model, which produces the estimates used to calculate SRR, takes the form:

$$\log \frac{p_{ijk}}{1 - p_{ijk}} = \gamma_i + \alpha_j + \beta^T Z_{ijk} , \qquad (1)$$

where p_{ijk} represents the probability of an unplanned readmission for the k^{th} discharge among patients from the i^{th} facility who are discharged from j^{th} hospital, and Z_{ijk} represents the set of patient-level characteristics. Here, γ_i is the fixed effect for facility and α_j is the random effect for hospital j. It is assumed that the α_j s arise as independent normal variables (i.e., $\alpha_j \sim N(0, \sigma^2)$).

• We then use the estimates from this model to calculate each facility's SRR:

$$SRR_i = \frac{o_i}{E_i} = \frac{o_i}{\sum_{j \in H(i)} \sum_{k=1}^{n_{ij}} \tilde{p}_{ijk}},$$
(2)

where, for the *i*th facility, O_i is the number of observed unplanned readmissions, E_i is the expected number of unplanned readmissions for discharges, H(i) is the collection of indices of hospitals from which patients are discharged, and \tilde{p}_{ijk} is the predicted probability of unplanned readmission under the national norm for each discharge. Specifically, \tilde{p}_{ijk} takes the form

$$\tilde{p}_{ijk} = \frac{\exp(\hat{\gamma_M} + \hat{\alpha}_j + \hat{\beta}^T Z_{ijk})}{1 + \exp(\hat{\gamma_M} + \hat{\alpha}_j + \hat{\beta}^T Z_{ijk})},$$
(3)

which estimates the probability that a discharge from hospital *j* of an individual in facility *i* with characteristics Z_{ijk} would result in an unplanned readmission if the facility effect corresponded to the median of national facility effects, denoted by $\widehat{\gamma}_M$. Here, $\widehat{\alpha}_j$ and $\widehat{\beta}$ are estimates from model (1). The sum of these probabilities is the expected number of unplanned readmissions E_i at facility *i*; e.g., the number of readmissions that would have been expected in facility *i* had they progressed to the readmissions at the same rate as the national population of dialysis patients.

Patient-Level Risk Adjustors

As mentioned previously, the model accounts for a set of patient-level characteristics:

- Sex
- Age
- Years on dialysis
- Diabetes as cause of ESRD
- BMI at incidence of ESRD
- Length (days) of index hospitalization
- Past-year comorbidities: We identify all unique ICD-9 diagnosis codes from each patient's prior year of Medicare claims. We group these diagnosis codes by diagnosis area using HHS' Hierarchical Condition Categories (CCs). The CCs used in calculation of the SRR are:
 - o <u>CCs 177, 178</u>: Amputation status
 - o <u>CC 108</u>: COPD
 - <u>CC 79</u>: Cardiorespiratory failure/shock
 - o <u>CC 46</u>: Coagulation defects & other specified hematological disorders
 - o <u>CCs 51, 52</u>: Drug and alcohol disorders
 - o <u>CCs 25, 26</u>: End-Stage Liver Disease
 - <u>CC 109</u>: Fibrosis of lung or other chronic lung disorders
 - <u>CCs 67–69, 100, 101</u>: Hemiplegia, paraplegia, paralysis
 - <u>CC 158</u>: Hip fracture/dislocation
 - <u>CC 174</u>: Major organ transplants (excl. kidney)
 - o <u>CC 7</u>: Metastatic cancer/acute leukemia
 - <u>CC 44</u>: Other hematological disorders
 - <u>CCs 6, 111–113</u>: Other infectious disease & pneumonias
 - <u>CCs 10–12</u>: Other major cancers
 - <u>CC 32</u>: Pancreatic disease
 - <u>CCs 54–56, 58, 60</u>: Psychiatric comorbidity
 - <u>CC 77</u>: Respirator dependence/tracheostomy status
 - o <u>CC 38</u>: Rheumatoid arthritis & inflammatory connective tissue disease
 - <u>CC 74</u>: Seizure disorders & convulsions
 - o <u>CC 2</u>: Septicemia/shock
 - o <u>CCs 8,9</u>: Severe cancer
 - <u>CCs 1, 3–5</u>: Severe infection
 - o <u>CCs 148, 149</u>: Ulcers
- Discharged with high-risk condition: We define a *high-risk* diagnosis as any diagnosis area that was rare in our population but had a 30-day readmission rate of at least 40%. We did not include high-risk diagnosis groups related to cancer or mental health. We group these conditions using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS). The CCS areas identified as high-risk are:
 - <u>CCS 5</u>: HIV infection
 - o <u>CCS 6</u>: Hepatitis
 - <u>CCS 56</u>: Cystic fibrosis
 - <u>CCS 57</u>: Immunity disorders
 - <u>CCS 61</u>: Sickle cell anemia
 - o <u>CCS 190</u>: Fetal distress and abnormal forces of labor
 - <u>CCS 151</u>: Other liver diseases
 - o <u>CCS 182</u>: Hemorrhage during pregnancy; abruptio placenta; placenta previa

- <u>CCS 186</u>: Diabetes or abnormal glucose tolerance complicating pregnancy; childbirth; or the puerperium
- o <u>CCS 210</u>: Systemic lupus erythematosus and connective tissue disorders
- <u>CCS 243</u>: Poisoning by nonmedicinal substances

The coefficients for the patient characteristics resulting from the logistic model are shown below.

Table 1. Effects of Patient Characteristics on Readmission Rates for Medicare-Covered Dialysis Patients, 2009

Patient Characteristic	Beta	SE	p		
Age (y)					
<25	0.33	0.03	<.0001		
25–45	0.18	0.01	<.0001		
45–60 (ref)	—	—	—		
60–75	-0.03	0.01	<.0001		
>75	0.06	0.01	<.0001		
BMI	•		•		
Underweight	0.08	0.01	<.0001		
Normal Weight (ref)	—	—	—		
Overweight	-0.05	0.01	<.0001		
Obese	-0.12	0.01	<.0001		
Cause of ESRD: Diabetes	0.05	0.01	<.0001		
Comorbidity (past year)	•				
Amputation status	0.06	0.01	<.0001		
COPD	0.22	0.01	<.0001		
Cardiorespiratory	0.23	0.01	<.0001		
failure/shock					
Coagulation defects & other	0.13	0.01	<.0001		
specified hematological					
disorders					
Drug and alcohol disorders	0.32	0.02	<.0001		
End-Stage Liver Disease	0.27	0.02	<.0001		
Fibrosis of lung or other	0.04	0.02	0.01		
chronic lung disorders					
Hemiplegia, paraplegia,	0.08	0.01	<.0001		
paralysis					
Hip fracture/dislocation	0.01	0.02	0.17		
Major organ transplants	-0.04	0.03	0.04		
(excl. kidney)					
Metastatic cancer/acute	0.29	0.04	<.0001		
leukemia					
Other hematological	0.18	0.02	<.0001		
disorders					
Other infectious disease &	0.15	0.01	<.0001		
pneumonias					
Other major cancers	0.02	0.01	0.04		
Pancreatic disease	0.21	0.01	<.0001		
Psychiatric comorbidity	0.19	0.01	<.0001		

Patient Characteristic	Beta	SE	p
Respirator	-0.03	0.04	0.11
dependence/tracheostomy			
status			
Rheumatoid arthritis &	0.02	0.02	0.06
inflammatory connective			
tissue disease			
Seizure disorders &	0.10	0.01	<.0001
convulsions			
Septicemia/shock	0.13	0.01	<.0001
Severe cancer	0.15	0.02	<.0001
Severe infection	0.06	0.02	0.0002
Ulcers	0.10	0.01	<.0001
Length of Index Hospitalization	on (days)		
Quartile 1 (ref)	—	—	-
Quartile 2	0.12	0.01	<.0001
Quartile 3	0.23	0.01	<.0001
Quartile 4	0.44	0.01	<.0001
Presence of high-risk	0.49	0.03	<.0001
diagnosis at index discharge			
Sex: Female	0.06	0.01	<.0001
Time on ESRD (y)			
<1 (ref)	—	—	—
1-2	0.000	0.01	0.25
	2		
2–3	-0.32	0.01	<.0001
3–6	-0.35	0.01	<.0001
>6	-0.38	0.01	<.0001

For more information on the diagnosis codes for the comorbid risk factors as defined in CCs, a crosswalk of CCs to ICD-9-CM codes is available at: (http://www.qualitynet.org) > Hospitals – Inpatient > Claims-Based Measures > Readmission Measures > Resources.

For more information on the diagnosis codes for the discharge diagnosis categories as defined in the CCSs, a crosswalk of CCS categories to ICD-9-CM codes is available at: (http://www.qualitynet.org) > Hospitals – Inpatient > Claims-Based Measures > Readmission Measures > Resources. AHRQ has also developed a crosswalk of CCs to ICD-10-CM codes, which will be used after national implementation of ICD-10 coding on CMS claims: http://www.hcup-us.ahrq.gov/toolssoftware/icd_10/ccs_icd_10.jsp.

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To estimate the probability of 30-day unplanned readmission, we use a three-stage model, the first of which is a fixed-effects logistic regression model. In this step, facility-hospital combinations are included as fixed effects, adjusting for a set of patient-level characteristics. The results of this step are estimates of the regression coefficients of patient-level characteristics in the logistic regression model. These estimates avoid issues of bias that arise through estimation of regression coefficients in a model with random effects. In particular, these estimates are unbiased regardless of correlations between hospital effects or facility effects and patient-case mix. These estimated regression coefficients are then used as an offset variable in the second stage model.

The next stage is a double random-effects logistic regression model. In this stage of the model, both dialysis facilities and hospitals are represented as random effects, and the sum of regression adjustments multiplied by estimated parameters obtained in the first stage is included as the offset variable. From this model, we obtain the estimated standard deviation of the random effects of hospitals [1].

The third stage of the model is a mixed-effects logistic regression model, in which dialysis facilities are modeled as fixed effects and hospitals are modeled as random effects, with the standard deviation specified as equal to its estimate from the second-stage model and the estimated parameters obtained in the first stage providing an offset. The expected number of readmissions for each facility is estimated as the sum of the probabilities of readmission of all index discharges in this facility and assuming the national norm (i.e., the median) for the facility effect. This model accounts for a given facility's case mix using the same set of patient-level characteristics as those in the first model.

The model and methods are described in some additional detail below:

• To estimate the probability of 30-day unplanned readmission following an index discharge, we use a three-stage approach. The main model, which produces the estimates used to calculate SRR, takes the form:

$$\log \frac{p_{ijk}}{1 - p_{ijk}} = \gamma_i + \alpha_j + \beta^T Z_{ijk} , \qquad (1)$$

where p_{ijk} represents the probability of an unplanned readmission for the k^{th} discharge among patients who are discharged from j^{th} hospital to the i^{th} facility, and Z_{ijk} represents the set of patient-level characteristics. Here, γ_i is the fixed effect for facility and α_j is the random effect for hospital j. It is assumed that the α_j s arise as independent normal variables (i.e., $\alpha_i \sim N(0, \sigma^2)$).

• We then use the estimates from this model to calculate each facility's SRR:

$$SRR_i = \frac{o_i}{E_i} = \frac{o_i}{\sum_{j \in H(i)} \sum_{k=1}^{n_{ij}} \tilde{p}_{ijk}},$$
(2)

where, for the *i*th facility, O_i is the number of observed unplanned readmissions, E_i is the expected number of unplanned readmissions for discharges, H(i) is the collection of indices of hospitals from which patients are discharged, and \tilde{p}_{ijk} is the predicted probability of unplanned readmission under the national norm for each discharge. Specifically, \tilde{p}_{ijk} takes the form

$$\tilde{p}_{ijk} = \frac{\exp(\hat{\gamma_M} + \hat{\alpha}_j + \hat{\beta}^T Z_{ijk})}{1 + \exp(\hat{\gamma_M} + \hat{\alpha}_j + \hat{\beta}^T Z_{ijk})},$$
(3)

which estimates the probability that a discharge from hospital *j* of an individual in facility *i* with characteristics Z_{ijk} would result in an unplanned readmission if the facility effect corresponded to the median of national facility effects, denoted by $\widehat{\gamma}_M$. Here, $\widehat{\alpha}_j$ and $\widehat{\beta}$ are estimates from model (1). The sum of these probabilities is the expected number of unplanned readmissions E_i at facility *i*; e.g.,

the number of readmissions that would have been expected in facility *i* had they progressed to the readmissions at the same rate as the national population of dialysis patients.

1. Diggle PJ, Heagerty P, Liang K-Y, Zeger SL. Analysis of Longitudinal Data. 2 New York: Oxford Univ. Press; 2002.

Patient-Level Risk Adjustors

As mentioned previously, the model accounts for a set of patient-level characteristics:

- Sex
- Age
- Years on dialysis
- Medicare Advantage status at discharge
- Nursing home status in past year at discharge
 - None (0 days)
 - Short term (<90 days)
 - Long term (>=90 days)
- Diabetes as cause of ESRD
- Interaction of age and diabetes as cause of ESRD
- BMI at incidence of ESRD*
 - o **< 18.5)**
 - o **18.5 24.9**
 - o **25-29.9**
 - o **30+**
 - *missing included with the 30+ group
- Length (days) of index hospitalization
- Past-year comorbidities: We identify all unique ICD-10 diagnosis codes from each patient's prior year of Medicare inpatient claims. We group these diagnosis codes by diagnosis area using the v2019.1 Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS) diagnosis categories. The CCS diagnosis categories used in calculation of the SRR are:
 - o CCS 6: Hepatitis
 - CCS 10: Immunizations and screening for infectious disease
 - CCS 42: Secondary malignancies
 - o CCS 50: Diabetes mellitus with complications
 - o CCS 51: Other endocrine disorders
 - CCS 52: Nutritional deficiencies
 - o CCS 55: Fluid and electrolyte disorders
 - CCS 59: Deficiency and other anemia
 - CCS 64: Other hematologic conditions
 - CCS 95: Other nervous system disorders
 - CCS 96: Heart valve disorders
 - CCS 97: Peri-; endo-; and myocarditis; cardiomyopathy (except that caused by tuberculosis or sexually transmitted disease)
 - CCS 100: Acute myocardial infarction
 - o CCS 101: Coronary atherosclerosis and other heart disease

- o CCS 102: Nonspecific chest pain
- CCS 106: Cardiac dysrhythmias
- o CCS 107: Cardiac arrest and ventricular fibrillation
- CCS 108: Congestive heart failure; nonhypertensive:
- CCS 117: Other circulatory disease
- o CCS 118: Phlebitis; thrombophlebitis and thromboembolism
- CCS 120: Hemorrhoids
- o CCS 121: Other diseases of veins and lymphatics
- CCS 122: Pneumonia (except that caused by tuberculosis or sexually transmitted disease)
- o CCS 127: Chronic obstructive pulmonary disease and bronchiectasis
- o CCS 130: Pleurisy; pneumothorax; pulmonary collapse
- o CCS 131: Respiratory failure; insufficiency; arrest (adult)
- o CCS 133: Other lower respiratory disease
- CCS 134: Other upper respiratory disease
- o CCS 135: Intestinal infection
- CCS 138: Esophageal disorders
- CCS 140: Gastritis and duodenitis
- o CCS 141: Other disorders of stomach and duodenum
- CCS 151: Other liver diseases
- o CCS 152: Pancreatic disorders (not diabetes)
- o CCS 153: Gastrointestinal hemorrhage
- o CCS 154: Noninfectious gastroenteritis
- o CCS 155: Other gastrointestinal disorders
- o CCS 158: Chronic kidney disease
- o CCS 159: Urinary tract infections
- CCS 197: Skin and subcutaneous tissue infections
- CCS 198: Other inflammatory condition of skin
- o CCS 199: Chronic ulcer of skin
- CCS 201: Infective arthritis and osteomyelitis (except that caused by tuberculosis or sexually transmitted disease)
- o CCS 237: Complication of device; implant or graft
- o CCS 244: Other injuries and conditions due to external causes
- o CCS 251: Abdominal pain
- o CCS 253: Allergic reactions
- o CCS 255: Administrative/social admission
- o CCS 259: Residual codes; unclassified
- o CCS 651: Anxiety disorders
- o CCS 659: Schizophrenia and other psychotic disorders
- CCS 660: Alcohol-related disorders
- o CCS 661: Substance-related disorders
- Discharged with high-risk condition: We define a *high-risk* diagnosis as any diagnosis area that was rare in our population but had a 30-day readmission rate of at least 40%. We did not include high-risk diagnosis groups related to cancer or mental health. We group these conditions using the

Agency for Healthcare Research and Quality (AHRQ) Clinical Classifications Software (CCS). The CCS areas identified as high-risk are:

- CCS 5: HIV infection
- CCS 6: Hepatitis
- o CCS 56: Cystic fibrosis
- o CCS 57: Immunity disorders
- o CCS 61: Sickle cell anemia
- o CCS 190: Fetal distress and abnormal forces of labor
- CCS 151: Other liver diseases
- o CCS 182: Hemorrhage during pregnancy; abruptio placenta; placenta previa
- CCS 186: Diabetes or abnormal glucose tolerance complicating pregnancy; childbirth; or the puerperium
- o CCS 210: Systemic lupus erythematosus and connective tissue disorders
- o CCS 243: Poisoning by nonmedicinal substances

2b3.2. If an outcome or resource use component measure is <u>not risk adjusted or stratified</u>, provide <u>rationale</u> <u>and analyses</u> to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities. N/A

2b3.3a. Describe the conceptual/clinical <u>and</u> statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g., potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p*<0.10; correlation of *x* or higher; patient factors should be present at the start of care) Also discuss any "ordering" of risk factor inclusion; for example, are social risk factors added after all clinical factors?

The list of covariates considered was based on CMS' Hospital-Wide All-Cause Readmission Rate (HWR; NQF #1789) and CMS' Standardized Hospitalization Ratio (SHR; NQF #1463), all of which were statistically verified by the measure developer.¹ The HWR and SHR adjusted for patient comorbidities measured at different points in time (prevalent and at ESRD incidence, respectively). Based on TEP input, we chose as a starting point the HWR comorbidity adjustments which are defined using claims data and can capture current comorbidities. There are concerns about the use of current comorbidities as adjustments in the SHR because they may reflect results of poor treatment and so lie in the causal path leading to hospitalization. These concerns are less salient when considering readmission since, whatever the cause of hospitalization, effective treatment and coordination to avoid readmission is important. In addition, we included length of the index hospitalization and severity of the index diagnosis as additional adjustments.

The risk adjustment is based on a two-stage logistic model. The adjustment is made for patient age, sex, diabetes, duration of ESRD, BMI at incidence, prior-year comorbidities, length of hospital stay and presence of a high-risk diagnosis at discharge. In the first stage of this model, both dialysis facilities and hospitals are represented as random effects, and regression adjustments are made for the set of patient-level characteristics listed above. From this first stage, we obtain the estimated standard deviation of the random effects of hospitals.

The second stage of the model is a mixed-effects model, in which facilities are fixed effects and hospitals are modeled as random effects, with the standard deviation specified as equal to its estimate from the first stage.

The expected number of readmissions for each facility is estimated as the summation of the probabilities of readmission for the discharges of all patients in this facility, assuming the national average or norm for facility effect. This model accounts for a given facility's case mix using the same set of patient-level characteristics as those in the first stage.

Relevant references are below^{2,3}; we conducted all analyses in R and SAS. The analyses presented here are based on ICD-9 codes; a crosswalk of ICD-9 to ICD-10 codes is presented in the Appendix.

1. Horwitz L, Partovian C, Lin Z, et al. "Hospital-wide all-cause risk-standardized readmission measure: Measure methodology report." Technical paper submitted to the Centers for Medicare and Medicaid Services. September 27, 2011. Available at http://www.naph.org/Unpublished-Documents/Hospital-Wide-All-Condition-30-Day-Risk-Standardized-Readmission- Measure.aspx. Accessed December 6, 2012.

2. He K, Kalbfleisch JD, Li Y, Li Y. "Evaluating readmission rates in dialysis facilities with or without adjustment for hospital effects." Unpublished manuscript. 2012.

3. Diggle PJ, Heagerty P, Liang KY, Zeger SL. Analysis of Longitudinal Data (2nded). Oxford University Press; Oxford. 2002.

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The risk adjustment is based on a three-stage logistic model. The adjustment is made for patient age, sex, diabetes, duration of ESRD, Medicare Advantage status at discharge, nursing home history in past year, BMI at incidence, prior-year comorbidities, length of hospital stay and presence of a high-risk diagnosis at discharge. In the first stage of this model, facility-hospital combinations are included as fixed effects, and regression adjustments are made for the set of patient-level characteristics listed above. From this first stage, we obtain the estimated regression coefficients which are then used as an offset variable in the second stage model. This avoids bias in regression coefficient estimates that can occur when fitting a randoma effects model if the covariates are correlated with the unknown facility or hospital effects.

The second stage is a double random-effects logistic regression model where both dialysis facilities and hospitals are represented as random effects, and the sum of regression adjustments multiplied by estimated parameters obtained in the first stage is included as the offset variable. From this model, we obtain the estimated standard deviation of the random effects of hospitals.

The third stage of the model is a mixed-effects model, in which facilities are fixed effects and hospitals are modeled as random effects, with the standard deviation specified as equal to its estimate from the second stage. Eestimated parameters obtained in the first stage are included as an offset. The expected number of readmissions for each facility is estimated as the sum of the estimated probabilities of readmission given the discharges of all patients in this facility, assuming the national average or norm for facility effect.

The list of 53 past-year comorbidity variables are selected from 233 indicators of AHRQ CCS diagnosis categories with prevalence greater than 0.1% using a score-test based sample splitting forward selection approach. In particular, the data sample is randomly split into two halves. The first half is used for fitting a first-stage fixed effects logistic regression model to select a set of comorbidity variables via a forward selection scheme using single variable score tests with 0.01 p-value cutoff and adjusting for patient-level characteristics such as age splines, sex, BMI, etc. The second half is then used to fit another first-stage model adjusting for patient-level risk factors as well as those selected variables using the first-half data sample. Single variable score tests are performed after model fitting to obtain p-values for selected variables. A common p-value of 1 is assigned to unselected variables using the first-half data sample. The steps above are repeated 50 times to generate 50 sets of p-values for all 233 variables. The 50 p-values of each variable are aggregated following Bühlmann and van de Geer and the 53 prevalent comorbidities with aggregated p-values less than 0.01 are selected.

Relevant references are below [1-3]; we conducted all analyses in R and SAS.

- 1. He K, Kalbfleisch JD, Li Y, Li Y. "Evaluating readmission rates in dialysis facilities with or without adjustment for hospital effects." Unpublished manuscript. 2012.
- 2. Diggle PJ, Heagerty P, Liang KY, Zeger SL. *Analysis of Longitudinal Data (2nd ed)*. Oxford University Press; Oxford. 2002.
- 3.Bühlmann, P. and van de Geer, S. (2011). Statistics for High-Dimensional Data: Methods, Theory and Applications. Springer.

2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

- Published literature
- 🛛 Internal data analysis
- Other (please describe)

The relationship among patient level SDS, socioeconomic disadvantage and health care utilization such as hospitalization is well-established in the general population and has received considerable attention over the years. (AHRQ Reports, 2011; 2012; 2013; 2014; 2015). The likelihood of hospitalization is related to socioeconomic disadvantage through differences in health status, insurance coverage, and access to quality primary care (Basu et al, 2012; Blustein et al, 1998). Further, individual and market or area-level measures of deprivation have been shown to contribute independently to preventable hospitalizations (Moy et al, 2013).

Health care outcomes and utilization are associated with area-level income and residential segregation, but particularly so for racial minorities (Williams, 2006; Williams and Collins, 2001). This suggests the interplay of patient level (race) and area level SES factors related to lower income, neighborhood poverty, segregation, levels of educational attainment, and unemployment levels that jointly influence key health outcomes related to morbidity (Williams 2006; Williams and Collins, 2001; AHRQ, 2008).

Within the dialysis population area-level SES are associated with poor outcomes (Almachraki et al 2016); while patient level factors such as race are predictive of differences in certain clinical outcomes by race. (Yan et al 2014; Whittle et al 1991). In a study of first year hemodialysis patients, patients of Hispanic ethnicity had lowest all-cause hospital length of stay compared to whites, while patients of black race had intermediate all-cause hospital admissions that was lower relative to whites but higher than Hispanic patient, with differences observed across certain age groups (Yan et al, CJASN 2014). Moreover the study authors found that infection-related hospitalizations were significantly higher for black and Hispanic patients compared to non-Hispanic whites. These associations could indicate certain facility level practices related to effective infection control and prevention may unevenly impact patients of black race and Hispanic ethnicity (Yan et al CJASN 2014 p7).

Insurance status is also related to health outcomes but this has not been studied extensively within the dialysis population as it relates to hospitalization, though the association has been documented in studies of the general dual Medicare and Medicaid population. Dual eligibles typically have greater comorbidity burden, face access to care barriers which in turn drive higher hospital utilization (Jiang et al, 2010; Moon and Shin,2006; Wright et al., 2015).

Maintaining employment is a challenge for dialysis patients which in turn can influence well-being and may have a proximal impact on outcomes such as hospitalization (Curtin et al, AJKD 1996).

Given these observed linkages we tested these patient- and area-level SDS/SES variables based on the conceptual relationships as described above and demonstrated in the literature, as well as the availability of data for the analyses. In total, we tested the following variables:

Patient level:

- Employment status 6 months prior to ESRD
- Sex
- Race
- Ethnicity
- Medicare dual eligible
- ZIP code level Area Deprivation Index (ADI) from Census data (2009-2013). Based on patient zipcode. We use the publicly available Area Deprivation Index (ADI) originally developed by Singh and colleagues at the University of Wisconsin. We applied the updated ADI based on 2009-2013 census data (University of Wisconsin, 2013 v1.5). The ADI reflects a full set of SES characteristics, including measures of income, education, and employment status, measured at the ZIP code level.

References:

Agency for Healthcare Research and Quality, Rockville, MD. Internet Citation: Chapter 3: Creation of New Race-Ethnicity Codes and SES Indicators for Medicare Beneficiaries - Chapter 3. January 2008. Publication # 08-0029-EF. <u>http://archive.ahrq.gov/research/findings/final-reports/medicareindicators/medicareindicators3.html</u>

Agency for Healthcare Research and Quality (AHRQ). 2010 National Health Care Disparities Report. Washington, DC: AHRQ; 2011).

Agency for Healthcare Research and Quality (AHRQ). 2011 National Health Care Disparities Report. Washington, DC: AHRQ; 2012).

Agency for Healthcare Research and Quality (AHRQ). 2012 National Health Care Disparities Report. Washington, DC: AHRQ; Reports: 2013).

Agency for Healthcare Research and Quality (AHRQ). 2013 National Health Care Disparities Report. Washington, DC: AHRQ; Reports: 2014).

Agency for Healthcare Research and Quality (AHRQ). 2014 National Health Care Disparities Report. Washington, DC: AHRQ; 2015).

Almachraki F, Tuffli M, Lee P, Desmarais M, Shih HC, Nissenson A, and Krishnan M. Population Health Management. Volume 19, Number 1, 2016.

Basu, J., Thumula, V., and Mobley, L.R. (2012, July-September). Changes In Preventable Hospitalization Patterns Among Adults. A Small Area Analysis Of U.S. States. Journal of Ambulatory Care Management 35(3), pp.3280-3290

J Blustein, K Hanson and S Shea. Preventable Hospitalizations And Socioeconomic Status. Health Affairs 17, no.2 (1998):177-189).

Curtin R, Oberley E, Sacksteder P, and Friedman A. Differences Between Employed and Nonemployed Dialysis Patients. AJKD Vol 27:4. (April) 1996. 533-540.

J. F. Lawless and C. Nadeau. Some Simple Robust Methods for the Analysis of Recurrent Events Technometrics. Vol. 37, No. 2 (May, 1995), pp. 158-168

Cox DR: Regression models and life tables (with discussion). JRStat Soc [SerB]34: 187–220, 1972

Jiang H, Wier L, Potter DEB, Burgess J. AHRQ Statistical Brief #96 Potentially Preventable Hospitalizations among Medicare-Medicaid Dual Eligibles, September 2010.

Kalbfleisch JD, Prentice RL: The statistical analysis of failure time data, Hoboken, New Jersey, John Wiley & Sons, Inc., 2002

Liu, D., Schaubel, D.E. and Kalbfleisch, J.D. (2012). Computationally efficient marginal models for clustered recurrent event data. Biometrics, 68, 637-647.

Moon S., Shin J. BMC Public Health. 2006 Apr 5;6:88. Health Care Utilization Among Medicare-Medicaid Dual Eligibles: A Count Data Analysis.

Moy E, Chang E, Barrett M. Potentially Preventable Hospitalizations — United States, 2001–2009. CDC Morbidity and Mortality Weekly Report (MMWR). Supplements November 22, 2013 / 62(03);139-143

Rodriguez R, Sen S, Mehta K, Moody-Ayers S, Bacchetti P, and O'Hare A. Geography Matters: Relationships among Urban Residential Segregation, Dialysis Facilities, and Patient Outcomes. Ann Intern Med. 2007; 146:493-501.

Singh, GK. Area Deprivation and Widening Inequalities In US Mortality, 1969–1998. Am J Public Health. 2003; 93(7):1137–1143.

University of Wisconsin School of Medicine Public Health. 2015 Area Deprivation Index v2.0. Downloaded from https://www.neighborhoodatlas.medicine.wisc.edu10/31/2018.

Williams D. "Race, Socioeconomic Status, and Health: The Added Effects of Racism and Discrimination. Annals of the New York Academy of Sciences. Volume 896, Issue 1, Article first published online: 6 FEB 2006.

Williams D, and Collins C, Racial Residential Segregation: A Fundamental Cause of Racial Disparities in Health. Public Health Reports / September–October 2001. Volume 116. 404-416.

Whittle JC, Whelton PK, Seidler AJ, Klag MJ. Does Racial Variation In Risk Factors Explain Black-White Differences In The Incidence Of Hypertensive End-Stage Renal Disease? Arch Intern Med. 1991 Jul;151(7):1359-64.

Wright B, Potter A, and Trivedi A. Federally Qualified Health Center Use Among Dual Eligibles: Rates Of Hospitalizations And Emergency Department Visits Health Affairs, 34, no.7 (2015):1147-1155.

Yan G, Norris K, Greene T, Yu A, Ma J, Yu W, and Cheung A. Race/Ethnicity, Age, and Risk of Hospital Admission and Length of Stay during the First Year of Maintenance Hemodialysis. Clin J Am Soc Nephrol 9: epub (June), 2014.

2b3.4a. What were the statistical results of the analyses used to select risk factors?

As described above, all risk factors included in the model have face validity, and all but four—being respirator-dependent, experiencing a hip fracture/dislocation or having rheumatoid arthritis at some point in the year leading up to hospitalization, and being within 2 years of ESRD incidence—are also significantly predictive of readmission (Table 2). As the ROC curve demonstrates, the model's accuracy is fair (Figure 2); c-statistic = 0.6359.

Table 2. Covariates Included in the SRR Model

Risk Factor	Beta	S	р
Age (y)			
<25	0.33	0.03	<.0001
25–45	0.18	0.01	<.0001
45–60 (ref)	—	_	_
60–75	-0.03	0.01	<.0001
>75	0.06	0.01	<.0001
BMI			
Underweight	0.08	0.01	<.0001
Normal Weight (ref)	—	_	_
Overweight	-0.05	0.01	<.0001
Obese	-0.12	0.01	<.0001
Cause of ESRD: Diabetes	0.05	0.01	<.0001
Comorbidity (past year)			
Amputation status	0.06	0.01	<.0001
COPD	0.22	0.01	<.0001
Cardiorespiratory failure/shock	0.23	0.01	<.0001
Coagulation defects & other specified hematological disorders	0.13	0.01	<.0001
Drug and alcohol disorders	0.32	0.02	<.0001
End-Stage Liver Disease	0.27	0.02	<.0001
Fibrosis of lung or other chronic lung disorders	0.04	0.02	0.01
Hemiplegia, paraplegia, paralysis	0.08	0.01	<.0001
Hip fracture/dislocation	0.01	0.02	0.17
Major organ transplants (excl. kidney)	-0.04	0.03	0.04
Metastatic cancer/acute leukemia	0.29	0.04	<.0001
Other hematological disorders	0.18	0.02	<.0001
Other infectious disease & pneumonias	0.15	0.01	<.0001
Other major cancers	0.02	0.01	0.04
Pancreatic disease	0.21	0.01	<.0001
Psychiatric comorbidity	0.19	0.01	<.0001
Respirator dependence/tracheostomy status	-0.03	0.04	0.11
Rheumatoid arthritis & inflammatory connective tissue disease	0.02	0.02	0.06
Seizure disorders & convulsions	0.10	0.01	<.0001
Septicemia/shock	0.13	0.01	<.0001
Severe cancer	0.15	0.02	<.0001
Severe infection	0.06	0.02	0.0002
Ulcers	0.10	0.01	<.0001
Length of Index Hospitalization (days)			
Quartile 1 (ref)		_	_
Quartile 2	0.12	0.01	<.0001

Risk Factor	Beta	S	p
Quartile 3	0.23	0.01	<.0001
Quartile 4	0.44	0.01	<.0001
Presence of high-risk diagnosis at index discharge	0.49	0.03	<.0001
Sex: Female	0.06	0.01	<.0001
Time on ESRD (y)			
<1 (ref)	_	_	—
1–2	0.00	0.01	0.25
2–3	-0.32	0.01	<.0001
3–6	-0.35	0.01	<.0001
>6	-0.38	0.01	<.0001

Note. Discharge diagnoses that were relatively rare but led to a 30-day unplanned readmission in at least 40% of cases.

Figure 2. ROC curve for SRR model (c-statistic = 0.6359).

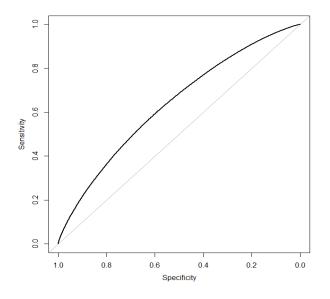
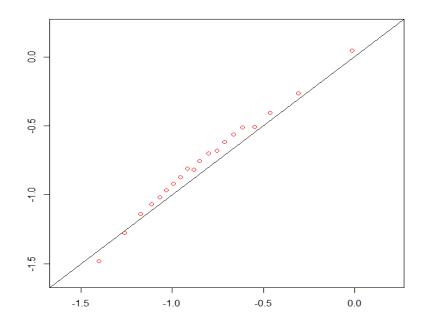


Figure 3. A plot of the logit of the observed proportion of admissions against the logit of model estimated probabilities to assess overall model fit.



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All but three risk factors included in the model—being age spline 0-13, age spline 60+, and underweight BMI are also significantly predictive of readmission (Table 1). As the ROC curve demonstrates, the model's accuracy is fair (see section 2b3.6); c-statistic = 0.6768.

Patient Characteristic	Beta	SE	p
Age Spline [*] (0-13)	-0.02	0.02	0.3639
Age Spline [*] (14-59)	-0.01	0.0008	< 0.0001
Age Spline [*] (60+)	0.0009	0.0007	0.2038
Cause of ESRD: Diabetes	-0.04	0.01	0.0083
Diabetes ^t × Age Spline [*] (14-59)	0-0.003	0.001	0.0268
Diabetes ^t × Age Spline [*] (60)	0.002	0.001	0.0447
Sex: Female	0.05	0.01	< 0.0001
Presence of high-risk diagnosis at index discharge**	0.49	0.03	<0.0001
Time on ESRD (y)	<u>.</u>	<u>.</u>	
<1 (ref)	_	—	_
1–2	0.14	0.01	< 0.0001
2–3	0.14	0.01	< 0.0001
3–6	0.12	0.01	<0.0001
>6	0.09	0.01	<0.0001
BMI			
< 18.5)	0.03	0.02	0.1554
18.5 - 24.9(ref)	_	_	
25-29.9	-0.05	0.01	< 0.0001
30+	-0.08	0.01	< 0.0001
Length of Index Hospitalization (days)			
Quartile 1 (ref)	_	_	
Quartile 2	0.06	0.01	< 0.0001
Quartile 3	0.13	0.01	< 0.0001
Quartile 4	0.27	0.01	< 0.0001
Medicare Advantage	-0.09	0.01	< 0.0001
Nursing Home Status (past year)			
No days spent in nursing home	_	_	_
1 to 89 days spent in nursing home	0.05	0.01	< 0.0001
90 or more days spent in nursing home	-0.03	0.01	0.0205
Comorbidity (past year)			
CCS 6: Hepatitis	0.09	0.01	< 0.0001
CCS 10: Immunizations and screening for infectious disease	0.05	0.01	0.0003
CCS 42: Secondary malignancies	0.34	0.03	< 0.0001
CCS 50: Diabetes mellitus with complications	0.06	0.01	<0.0001
CCS 51: Other endocrine disorders	0.06	0.01	<0.0001
CCS 52: Nutritional deficiencies	0.10	0.01	<0.0001
CCS 55: Fluid and electrolyte disorders	0.15	0.01	<0.0001
CCS 59: Deficiency and other anemia	0.06	0.02	<0.0001
CCS 64: Other hematologic conditions	0.11	0.02	<0.0001
CCS 95: Other nervous system disorders	0.11	0.01	< 0.0001
CCS 96: Heart valve disorders	0.06	0.01	< 0.0001

Table 1. Effects of Patient Characteristics on Readmission Rates for Medicare-Covered Dialysis Patients, 2018

Patient Characteristic	Beta	SE	p
CCS 97: Peri-; endo-; and myocarditis; cardiomyopathy			
(except that caused by tuberculosis or sexually transmitted	0.06	0.01	< 0.0001
disease)			
CCS 100: Acute myocardial infarction	0.08	0.01	< 0.0001
CCS 101: Coronary atherosclerosis and other heart disease	0.07	0.01	< 0.0001
CCS 102: Nonspecific chest pain	0.09	0.01	< 0.0001
CCS 106: Cardiac dysrhythmias	0.09	0.01	<0.0001
CCS 107: Cardiac arrest and ventricular fibrillation	-0.08	0.02	0.0006
CCS 108: Congestive heart failure; nonhypertensive	0.07	0.01	< 0.0001
CCS 117: Other circulatory disease	0.07	0.01	< 0.0001
CCS 118: Phlebitis; thrombophlebitis and	0.05	0.01	0.0001
thromboembolism	0.05	0.01	<0.0001
CCS 120: Hemorrhoids	0.08	0.02	< 0.0001
CCS 121: Other diseases of veins and lymphatics	0.07	0.01	< 0.0001
CCS 122: Pneumonia (except that caused by tuberculosis or			
sexually transmitted disease)	0.06	0.01	<0.0001
CCS 127: Chronic obstructive pulmonary disease and			
bronchiectasis	0.12	0.01	<0.0001
CCS 130: Pleurisy; pneumothorax; pulmonary collapse	0.08	0.01	< 0.0001
CCS 131: Respiratory failure; insufficiency; arrest (adult)	0.11	0.01	< 0.0001
CCS 133: Other lower respiratory disease	0.09	0.01	< 0.0001
CCS 134: Other upper respiratory disease	0.07	0.02	< 0.0001
CCS 135: Intestinal infection	0.13	0.01	< 0.0001
CCS 138: Esophageal disorders	0.05	0.01	< 0.0001
CCS 140: Gastritis and duodenitis	0.05	0.01	< 0.0001
CCS 141: Other disorders of stomach and duodenum	0.18	0.01	< 0.0001
CCS 151: Other liver diseases	0.12	0.01	< 0.0001
CCS 152: Pancreatic disorders (not diabetes)	0.14	0.02	< 0.0001
CCS 153: Gastrointestinal hemorrhage	0.14	0.01	< 0.0001
CCS 154: Noninfectious gastroenteritis	0.07	0.02	<0.0001
CCS 155: Other gastrointestinal disorders	0.09	0.01	< 0.0001
CCS 158: Chronic kidney disease	-0.30	0.06	< 0.0001
CCS 159: Urinary tract infections	0.06	0.01	< 0.0001
CCS 197: Skin and subcutaneous tissue infections	0.04	0.01	<0.0001
CCS 198: Other inflammatory condition of skin	0.16	0.02	<0.0001
CCS 199: Chronic ulcer of skin	0.10	0.01	<0.0001
CCS 201: Infective arthritis and osteomyelitis (except that	0.11	0.01	
caused by tuberculosis or sexually transmitted disease)	-0.08	0.01	<0.0001
CCS 237: Complication of device; implant or graft	0.07	0.01	< 0.0001
CCS 244: Other injuries and conditions due to external	0.07	0.01	<0.0001
causes	0.09	0.01	<0.0001
CCS 251: Abdominal pain	0.14	0.02	<0.0001
CCS 253: Allergic reactions	0.08	0.02	<0.0001
CCS 255: Administrative/social admission	0.15	0.01	<0.0001
CCS 259: Residual codes; unclassified	0.13	0.01	<0.0001
CCS 651: Anxiety disorders	0.03	0.01	<0.0001
CCS 659: Schizophrenia and other psychotic disorders	0.08	0.01	<0.0001
CCS 660: Alcohol-related disorders	0.19	0.02	<0.0001
CCS 661: Substance-related disorders	0.18	0.02	<0.0001
ככז טטב. שמשגמוונכיו כומופט מושטו מפוש	0.10	0.01	\U.UU1

* Three age spline variables centered at 60 are defined as (age-14) * I(age < 14), max(age-60,-46) * I(age<60), and (age-60) * I(age>=60), where I(•) denotes an indicator.

^t Diabetes as a cause of ESRD

** Discharge diagnoses that were relatively rare but led to a 30-day unplanned readmission in at least 40% of cases.

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors (e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.) Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk. 2019 Submission

While the inclusion of some patient SES characteristics such as employment 6 months prior to ESRD, Hispanic, Medicare Dual Eligible, and Asian are significant, other patient SES characteristics are not (Area Deprivation Index, Black, American Indian or Alaskan Native, and Other). The Pearson correlation between the model with and without the added SES characteristics is r=0.9989.

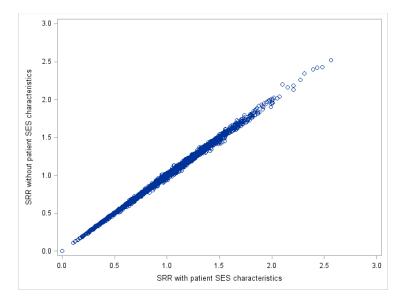
Table 2. Effects of Patient Characteristics (including SES) on Readmission Rates for Medicare-Covered Dialysis P	atients,
2018	

	Ba	seline Mode	el	Adjus	ted for SDS/	SES
Patient Characteristic				Beta	SE	p
Employed 6 months prior to ESRD				-0.05	0.01	<0.0001
Hispanic				-0.04	0.01	0.0049
Medicare Dual Eligible				0.06	0.01	<0.0001
Area Deprivation Index (patient zip				0.0004	0.0003	0.1749
code)				0.0004	0.0003	0.1749
Race						
White (ref)				_	_	_
Black				-0.02	0.01	0.0796
Asian or Pacific Islander				-0.08	0.02	0.0005
American Indian or Alaskan Native				0.03	0.04	0.5445
Other				-0.09	0.07	0.2045
Age Spline [*] (0-13)	-0.02	0.02	0.3639	-0.003	0.02	0.871
Age Spline [*] (14-59)	-0.01	0	< 0.0001	-0.01	0.0008	<0.0001
Age Spline [*] (60+)	0	0	0.2038	0.0008	0.0007	0.2753
Cause of ESRD: Diabetes	-0.04	0.01	0.0083	-0.05	0.01	0.0013
Diabetes ^t × Age Spline [*] (14-59)	0	0	0.0268	-0.003	0.001	0.0038
Diabetes ^t × Age Spline [*] (60)	0	0	0.0447	0.003	0.001	0.0108
Sex: Female	0.05	0.01	<0.0001	0.04	0.01	<0.0001
Presence of high-risk diagnosis at	0.49	0.03	<0.0001	0.49	0.03	<0.0001
index discharge	0.49	0.05	<0.0001	0.49	0.05	<0.0001
Time on ESRD (y)						
<1 (ref)	—	—	_	—	—	_
1–2	0.14	0.01	<0.0001	0.13	0.01	<0.0001
2–3	0.14	0.01	<0.0001	0.15	0.01	<0.0001
3–6	0.12	0.01	<0.0001	0.12	0.01	<0.0001
>6	0.09	0.01	<0.0001	0.09	0.01	<0.0001
BMI						
Underweight	0.03	0.02	0.1554	0.02	0.02	0.318
Normal Weight (ref)	_	_	_	_	_	
Overweight	-0.05	0.01	<0.0001	-0.04	0.01	0.0005
Obese	-0.08	0.01	<0.0001	-0.08	0.01	<0.0001
Length of Index Hospitalization (days)						

	Baseline Model		Adjus	ted for SDS/	SES	
Patient Characteristic				Beta	SE	р
Quartile 1 (ref)	_	_	_	_	_	_
Quartile 2	0.06	0.01	<0.0001	0.07	0.01	<0.0001
Quartile 3	0.13	0.01	< 0.0001	0.14	0.01	< 0.0001
Quartile 4	0.27	0.01	<0.0001	0.27	0.01	<0.0001
Medicare Advantage	-0.09	0.01	< 0.0001	-0.09	0.01	< 0.0001
Nursing Home Status (past year)						
No days spent in nursing home	_	_	_	_	_	
1 to 89 days spent in nursing home	0.05	0.01	<0.0001	0.04	0.01	<0.0001
90 or more days spent in nursing						
home	-0.03	0.01	0.0205	-0.05	0.01	0.0004
Comorbidity (past year)						
CCS 6: Hepatitis	0.09	0.01	< 0.0001	0.09	0.01	< 0.0001
CCS 10: Immunizations and screening						
for infectious disease	0.05	0.01	0.0003	0.06	0.01	<0.0001
CCS 42: Secondary malignancies	0.34	0.03	<0.0001	0.35	0.03	<0.0001
CCS 50: Diabetes mellitus with						
complications	0.06	0.01	<0.0001	0.06	0.01	<0.0001
CCS 51: Other endocrine disorders	0.06	0.01	< 0.0001	0.07	0.01	< 0.0001
CCS 52: Nutritional deficiencies	0.1	0.01	< 0.0001	0.10	0.01	< 0.0001
CCS 55: Fluid and electrolyte disorders	0.15	0.01	< 0.0001	0.15	0.01	< 0.0001
CCS 59: Deficiency and other anemia	0.06	0.02	< 0.0001	0.06	0.02	0.0002
CCS 64: Other hematologic conditions	0.11	0.02	< 0.0001	0.13	0.02	< 0.0001
CCS 95: Other nervous system						
disorders	0.11	0.01	<0.0001	0.12	0.01	<0.0001
CCS 96: Heart valve disorders	0.06	0.01	<0.0001	0.06	0.01	< 0.0001
CCS 97: Peri-; endo-; and myocarditis;						
cardiomyopathy (except that caused						
by tuberculosis or sexually transmitted	0.06	0.01	<0.0001	0.06	0.01	<0.0001
disease)						
CCS 100: Acute myocardial infarction	0.08	0.01	< 0.0001	0.09	0.01	< 0.0001
CCS 101: Coronary atherosclerosis and						
other heart disease	0.07	0.01	<0.0001	0.07	0.01	<0.0001
CCS 102: Nonspecific chest pain	0.09	0.01	<0.0001	0.11	0.01	<0.0001
CCS 106: Cardiac dysrhythmias	0.09	0.01	< 0.0001	0.09	0.01	< 0.0001
CCS 107: Cardiac arrest and						
ventricular fibrillation	-0.08	0.02	0.0006	-0.09	0.02	0.0001
CCS 108: Congestive heart failure;				0.00		
nonhypertensive	0.07	0.01	<0.0001	0.06	0.01	<0.0001
CCS 117: Other circulatory disease	0.07	0.01	<0.0001	0.06	0.01	< 0.0001
CCS 118: Phlebitis; thrombophlebitis						
and thromboembolism	0.05	0.01	<0.0001	0.05	0.01	<0.0001
CCS 120: Hemorrhoids	0.08	0.02	<0.0001	0.08	0.02	<0.0001
CCS 121: Other diseases of veins and						
lymphatics	0.07	0.01	<0.0001	0.09	0.01	<0.0001
CCS 122: Pneumonia (except that						
caused by tuberculosis or sexually	0.06	0.01	<0.0001	0.06	0.01	<0.0001
transmitted disease)						
CCS 127: Chronic obstructive	0.12	0.01	<0.0001	0.12	0.01	<0.0001

	Baseline Model		Adjus	ted for SDS/	'SES	
Patient Characteristic				Beta	SE	р
CCS 130: Pleurisy; pneumothorax;	0.08	0.01	<0.0001	0.09	0.01	<0.0001
pulmonary collapse	0.00	0.01	\0.0001	0.05	0.01	<0.0001
CCS 131: Respiratory failure;	0.11	0.01	<0.0001	0.11	0.01	<0.0001
insufficiency; arrest (adult)						
CCS 133: Other lower respiratory	0.09	0.01	<0.0001	0.09	0.01	<0.0001
disease						
CCS 134: Other upper respiratory disease	0.07	0.02	<0.0001	0.07	0.02	<0.0001
CCS 135: Intestinal infection	0.13	0.01	<0.0001	0.12	0.01	<0.0001
CCS 138: Esophageal disorders	0.15	0.01	<0.0001	0.12	0.01	<0.0001
CCS 140: Gastritis and duodenitis	0.05	0.01	<0.0001	0.05	0.01	<0.0001
CCS 141: Other disorders of stomach						
and duodenum	0.18	0.01	<0.0001	0.19	0.01	<0.0001
CCS 151: Other liver diseases	0.12	0.01	<0.0001	0.12	0.01	< 0.0001
CCS 152: Pancreatic disorders (not						
diabetes)	0.14	0.02	<0.0001	0.13	0.02	<0.0001
CCS 153: Gastrointestinal hemorrhage	0.14	0.01	<0.0001	0.14	0.01	<0.0001
CCS 154: Noninfectious gastroenteritis	0.07	0.02	<0.0001	0.10	0.02	<0.0001
CCS 155: Other gastrointestinal	0.09	0.01	<0.0001	0.09	0.01	<0.0001
disorders						
CCS 158: Chronic kidney disease	-0.3	0.06	<0.0001	-0.33	0.06	<0.0001
CCS 159: Urinary tract infections	0.06	0.01	<0.0001	0.05	0.01	<0.0001
CCS 197: Skin and subcutaneous tissue	0.04	0.01	<0.0001	0.05	0.01	<0.0001
infections						
CCS 198: Other inflammatory	0.16	0.02	<0.0001	0.15	0.02	<0.0001
condition of skin CCS 199: Chronic ulcer of skin	0.11	0.01	<0.0001	0.11	0.01	<0.0001
CCS 201: Infective arthritis and	0.11	0.01	<0.0001	0.11	0.01	<0.0001
osteomyelitis (except that caused by						
tuberculosis or sexually transmitted	-0.08	0.01	<0.0001	-0.09	0.01	<0.0001
disease)						
CCS 237: Complication of device;						
implant or graft	0.07	0.01	<0.0001	0.07	0.01	<0.0001
CCS 244: Other injuries and conditions	0.00	0.01	-0.0001	0.00	0.01	-0.0001
due to external causes	0.09	0.01	<0.0001	0.08	0.01	<0.0001
CCS 251: Abdominal pain	0.14	0.02	<0.0001	0.12	0.02	<0.0001
CCS 253: Allergic reactions	0.08	0.01	<0.0001	0.08	0.01	<0.0001
CCS 255: Administrative/social	0.15	0.01	<0.0001	0.15	0.01	<0.0001
admission						
CCS 259: Residual codes; unclassified	0.09	0.01	<0.0001	0.08	0.01	< 0.0001
CCS 651: Anxiety disorders	0.08	0.01	<0.0001	0.09	0.01	<0.0001
CCS 659: Schizophrenia and other	0.19	0.02	<0.0001	0.16	0.02	<0.0001
psychotic disorders						
CCS 660: Alcohol-related disorders	0.16	0.02	<0.0001	0.15	0.02	<0.0001
CCS 661: Substance-related disorders	0.18	0.01	<0.0001	0.16	0.01	<0.0001

Figure 2. Correlation between SRR with and without patient SES characteristics (2018).



Pearson r=0.9989.

Patient-level SDS: With the addition of patient and area SDS characteristics to the model, four characteristics were found to be statistically significant. Asian/Pacific Islander (OR 0.96, p=0.0005), employed 6 months prior to ESRD (OR 0.95, p < 0.0001), and Hispanic Patients (0.96, p=0.0049) have lower odds of a readmission while Medicare dual eligible patients have 6% higher odds of readmission (OR 1.06, p<0.0001).

We also examined how the different modeling approaches without and with SDS/SES adjustment changed how facilities were flagged in terms of their expected readmission. As shown in Table 3, the flagging rates changed nominally between the original SRR and the sensitivity model that includes SDS/SES.

	S	SRR with SDS/SES		
SRR without	Better than		Worse than	
SDS/SES	Expected	As Expected	Expected	Total
Better than Expected	122 (1.76)	9 (0.13)	0 (0.0)	131 (1.89)
As Expected	8 (0.12)	6,544 (94.33)	16 (0.23)	6,568 (94.68)
Worse than Expected	0 (0.0)	10 (0.14)	228 (3.29)	238 (3.43)
Total	130 (1.87)	6,563 (95.61)	244 (3.52)	6,937

Table 3. Comparison of Flagging rates for SRR with and with out SDS/SES adjustment, 2018 data

These results show that facility profiling changes nominally with the addition of these selected patient- or area-level SDS/SES factors. 244 (3.52%) facilities are flagged as worse than expected and 130 (1.87%) facilities are flagged as better than expected in the model adjusting for SDS/SES versus the SRR baseline model where 238 (3.43%) facilities are flagged as worse than expected and 131 (2.89%) facilities are flagged as better than expected. This empirical finding demonstrating nominal differences in flagging when adjusting for SDS/SES, coupled with the risk of reducing patients' access to high quality care supports the decision to not adjust SRR for the selected SDS/SES factors.

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model <u>or</u> stratification approach (*describe the steps*—*do not just name a method; what statistical analysis was used*)

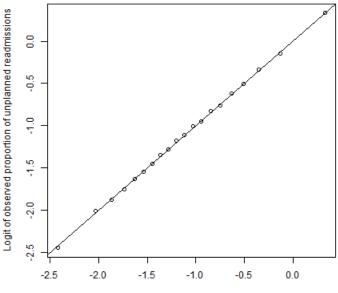
Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to <a>2b3.9

The model's fit is demonstrated in Figure 2, which compares the observed rates with the model-based predictions. We bin all observations into 20 groups based on their model-based predicted values and compute the observed readmission proportion for each group. We then apply the logit transformation to each group's observed readmission proportion and plot it against the same group's average linear prediction; see the dots for all 20 groups in the plot. The 45-degree line would represent a perfect match between the observed values and the model-based predictions. In general, the closer the observed values are to this line the better the model fit. As the figure shows, the observed values are spaced fairly equally and lie very close to the 45-degree line, indicating a good fit.

2019 Submission

Figure 3. A plot of the logit of the observed proportion of admissions against the logit of model estimated probabilities to assess overall model fit.



Logit of estimated probabilities of unplanned readmissions

The model's fit is demonstrated in Figure 3 (above), which compares the observed rates with the model-based predictions. We bin all observations into 20 groups based on their model-based predicted values and compute the observed readmission proportion for each group. We then apply the logit transformation to each group's observed readmission proportion and plot it against the same group's average linear prediction; see the dots for all 20 groups in the plot. The 45-degree line would represent a perfect match between the observed values and the model-based predictions. In general, the closer the observed values are to this line the better the model fit. As the figure shows, the observed values are spaced fairly equally and lie very close to the 45-degree line, indicating a good fit.

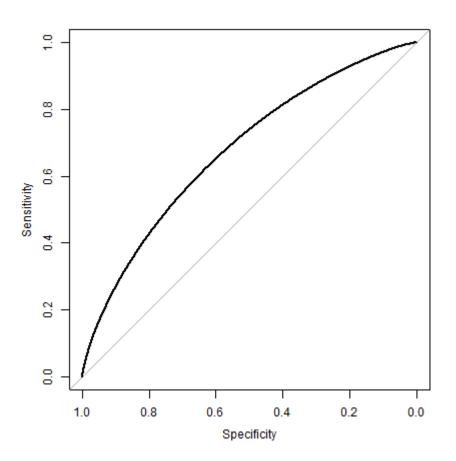
2b3.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R-squared):

As the ROC curve demonstrates, the model's accuracy is fair (Figure 2 above); c-statistic = 0.6359.

2019 Submission

As the ROC curve demonstrates, the model's accuracy is fair (Figure 4); c-statistic = 0.6768.

Figure 4. ROC curve for SRR model (c-statistic = 0.6768).



2b3.7. Statistical Risk Model Calibration Statistics (e.g., Hosmer-Lemeshow statistic):

The Hosmer-Lemeshow test statistic based on deciles of risk is 60.9 with P-value<0.0001 (df=8). In very large samples such as this even relatively small departures from the model (such as those illustrated in Figure 2) will lead to significant results. As noted earlier, Figure 2 illustrates that the model provides an overall good fit to the data.

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The Hosmer-Lemeshow test statistic based on deciles of risk is 7.05 with P-value=0.5314 (df=8), indicating that the model is a good fit. As illustrated in Figure 3, the model provides an overall good fit to the data.

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

The model's fit is demonstrated in Figure 3, which compares the observed rates with the model-based predictions. We bin all observations into 20 groups based on their model-based predicted values and compute the observed readmission proportion for each group. We then apply the logit transformation to each group's observed readmission proportion and plot it against the same group's average linear prediction; see the dots for all 20 groups in the plot. The 45-degree line would represent a perfect match between the observed values and the model-based predictions. In general, the closer the observed values are to this line the better the model fit.

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The model's fit is demonstrated in Figure 3, which compares the observed rates with the model-based predictions. We bin all observations into 20 groups based on their model-based predicted values and compute the observed readmission proportion for each group. We then apply the logit transformation to each group's observed readmission proportion and plot it against the same group's average linear prediction; see the dots for all 20 groups in the plot. The 45-degree line would represent a perfect match between the observed values and the model-based predictions. In general, the closer the observed values are to this line the better the model fit.

2b3.9. Results of Risk Stratification Analysis:

An assessment of the risk analysis is given in Figure 3 above.

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An assessment of the risk analysis is given in Figure 3 above. The 45-degree line would represent a perfect match between the observed values and the model-based predictions within each sub-group based on risk stratification.

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.e., what do the results mean and what are the norms for

the test conducted)

As Figure 3 shows, the observed values are spaced fairly equally and lie very close to the 45-degree line. This means that the model fit is good and therefore adequately adjusts for patient characteristics (case mix).

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As Figure 3 shows, the observed values are spaced fairly equally and lie very close to the 45-degree line. This means that the model fit is good and therefore adequately adjusts for patient characteristics (case mix).

2b3.11. Optional Additional Testing for Risk Adjustment (*not required*, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed)

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE 2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (*describe the steps*—*do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b*)

To test the null hypothesis that the SRR for a given facility is statistically different from the national average, we use a simulation method to calculate the nominal p-value as the probability that the observed number of readmissions should be at least as extreme as that expected. This calculation is based on the supposition that, having adjusted for case mix, this facility has a true readmission rate corresponding to the average facility. Our approach captures the most important aspects of the variability in the SRR. It also avoids difficulties with more traditional methods based on estimates and standard errors. Methods are described in detail in He et al. (2013).

2019 Submission

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2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined)

To address the problem of simultaneously monitoring a large number of facilities and to take account of the intrinsic unexplained variation among facilities, we used the approach described in Kalbfleisch and Wolfe (2013). This method is based on the empirical null as described in Efron (2004, 2007). The p-value for each facility is converted to a Z-score, stratified into three groups based on numbers of discharges within each facility. The empirical null corresponds to a normal curve that is fitted to the center of each Z-score histograms using a robust M-estimation method. The standard deviation of empirical null distribution is then used for a reference distribution (with mean 0) to identify outlier facilities. This method aims to separate underlying intrinsic variation in facility outcomes from variation that might be attributed to poor (or excellent) care.

The flagging rates presented in Table 4 are based on flagging those facilities in the upper tail (area=5%) of the empirical null distribution in each stratum. (The empirical null p-value is 5% or less.)

Facility Size (No. of Patients)	No. of Facilities	SRR: Worse than Expected				
Small (<=70)	1732	89 (5.14%)				
Medium (71–121)	1784	126 (7.06%)				
Large (>121)	1757	147 (8.37%)				
Total	5273	362 (6.87%)				

Table 4. Facilities Identified as Performing Worse than Expected for 30-Day Readmission Rate

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To address the problem of simultaneously monitoring a large number of facilities and to take account of the intrinsic unexplained variation among facilities, we used the approach described in Kalbfleisch and Wolfe (2013). This method is based on the empirical null as described in Efron (2004, 2007). The p-value for each

facility is converted to a Z-score, stratified into four groups based on patient-years within each facility. The empirical null corresponds to a normal curve that is fitted to the center of each Z-score histograms using a robust M-estimation method. The standard deviation of empirical null distribution is then used for a reference distribution (with mean 0) to identify outlier facilities. This method aims to separate underlying intrinsic variation in facility outcomes from variation that might be attributed to poor (or excellent) care.

The flagging rates presented in Table 6 are based on flagging those facilities in the upper tail (area=5%) of the empirical null distribution in each stratum. (The empirical null p-value is 5% or less.)

Facility Size (Patient-years)	No. of Facilities ¹	SRR: Worse than Expected
1 st Quartile	1,733	101 (5.83%)
2 nd Quartile	1,733	80 (4.62%)
3 rd Quartile	1,734	79 (4.56%)
4 th Quartile	1,733	145 (8.37%)
Total	6,933	405 (5.84%)

Table 4. Facilities Identified as Performing Worse than Expected for 4-30 Day Readmission Rate, 2018

¹ Four facilities did not receive a facility size.

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.e., what do the results mean in terms of statistical and meaningful differences?)

Without empirical null methods, a large number of facilities will be flagged, including many larger facilities with a relatively small difference between the rates of readmission. In contrast, the methods based on the empirical null make appropriate adjustments for overdispersion. Using this method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size.

2019 Submission

Without empirical null methods, a large number of facilities will be flagged, including many larger facilities with a relatively small difference between the rates of readmission. In contrast, the methods based on the empirical null make appropriate adjustments for overdispersion. Using this method, facilities are flagged if they have outcomes that are extreme when compared to the variation in outcomes for other facilities of a similar size.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS *If only one set of specifications, this section can be skipped*.

<u>Note</u>: This item is directed to measures that are risk-adjusted (with or without social risk factors) **OR** to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specification for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps*—*do not just name a method; what*

N/A

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

N/A

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.e., what do the results mean and what are the norms for the test conducted)

N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*) The SRR is dependent on Medicare claims and other CMS administrative data for several important components of measure calculation, including identification of comorbid conditions. For these reasons,, the SRR was originally developed and, subsequently implemented as, a measure limited to Medicare patients.

For several Medicare-only measures developed by UM-KECC, the presence of active Medicare coverage has been defined using a combination of criteria including a defined minimum of paid claims for dialysis services and/or presence of a Medicare inpatient claim during an eligibility period. With the recent increase in Medicare Advantage (MA) coverage for Medicare chronic dialysis patients, and the known systemic issue of unavailable outpatient claims data for MA patients, these criteria have the potential to introduce significant bias into measure calculations that could affect results for dialysis facilities with either very low or high MA patient populations.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (e.g., results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each)

As part of the comprehensive measure review process, we assessed the extent of MA coverage for ESRD dialysis patients and the effect of our historical definition of "active Medicare" status on the measure result. Medicare Advantage patient status was defined using Medicare Enrollment Database (EDB) criteria. Primary Medicare Fee for Service (FFS) coverage was identified using CMS administrative data, and active Medicare status utilized the combination of minimum dialysis paid claims and/or inpatient Medicare hospitalization claims briefly described above. We confirmed the presence of usable ICD diagnosis codes from MA inpatient claims and the nearly complete absence of outpatient Medicare claims data for patients identified as MA in the CMS data used for our measure calculation.

Summary findings:

1. The percentage of patients with MA coverage receiving chronic dialysis in US dialysis facilities has approximately doubled in the last decade and is approaching 20% based on 2017 data.

2. We confirmed the presence of usable ICD diagnosis codes from MA inpatient claims and the nearly complete absence of outpatient Medicare claims data for patients identified as MA in the CMS data used for our measure calculation

Additional analyses (Table 5) demonstrate a variable distribution of Medicare Advantage ESRD dialysis patient proportion following geographic boundaries. For example, the percentage of MA ESRD patient time at risk relative to total Medicare ESRD patient time at risk varies from a low of 2.2% in Wyoming to a high of 44.2% in Puerto Rico.

State	N	Mean (SD)
PR	44	44.2 (14.5)
RI	16	33.6 (18.5)
HI	31	27.8 (11.2)
ОН	323	26.8 (11.4)
PA	307	25 (14.5)
AZ	121	24.6 (12.5)
CA	658	23.9 (16.6)
MN	119	23.5 (10.6)
OR	71	22.9 (15.3)
MI	211	22.4 (10.1)
TN	185	21 (8.9)
AL	176	19.8 (10.5)
FL	456	19.6 (10.3)
СО	125	18.7 (8.9)
WI	80	18.7 (11)
ТХ	675	18.6 (10.9)
NY	353	17.2 (7.6)
GA	296	17.2 (8.8)
NV	49	16.9 (9.7)
WV	45	16.6 (8.2)
КҮ	120	16.2 (6.7)
МО	165	15.2 (9.1)
NC	220	14.9 (8.6)
SC	150	14.4 (6.6)
IN	166	14.2 (8.1)
LA	175	14 (10)
NM	54	13.9 (12.2)
IL	317	13.2 (9.5)
MA	84	13.1 (11.8)
NJ	48	12.7 (4.9)
СТ	179	12.7 (6.3)
VI	4	12.5 (25)
ID	43	12.1 (8.5)
UT	28	12.1 (8.9)
ME	17	11.6 (5.3)
WA	93	11 (8.5)
VA	189	10.9 (6.3)

Table 5. Average of Dialysis Facilities' Percent of MA Patients¹ by State, 2018.

State	N	Mean (SD)
AR	70	10.8 (6.4)
KS	57	9.3 (7.5)
IA	67	8.2 (6.6)
DC	86	7.8 (6.6)
MS	90	7.8 (5.1)
ОК	21	7.7 (10.1)
NE	166	7.4 (9.7)
MD	38	7.2 (7)
ND	16	6.7 (4.9)
DE	28	6.2 (4.6)
VT	8	5.5 (2.8)
SD	27	5.3 (6)
NH	19	4.8 (3.3)
MT	15	3.6 (3.7)
AK	9	2.3 (3.2)
WY	10	2.2 (3.2)
AS	1	0.6 (0)
GU	5	0.4 (0.4)
MP	2	0 (0)

¹ Each facility's percent of MA was based on patient assignment on January 1, 2018.

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and nonresponders) and how the specified handling of missing data minimizes bias? (i.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; <u>if no empirical analysis</u>, provide rationale for the selected approach for missing data)

Based on the above results, we have included Mediare Advantage patients in the measure, but have limited the identification of comorbidities to inpatient claims (which are available for patients of all insurance types) and added an adjustment factor to account for Medicare advantage patients in the model. This minimizes risk of biased results at the dialysis facility level and is consistent with a number of other NQF-endorsed measures that are based on Medicare claims data.

3. Feasibility

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

3a. Byproduct of Care Processes

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

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

Generated or collected by and used by healthcare personnel during the provision of care (e.g., blood pressure, lab value, diagnosis, depression score), Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims)

If other:

3b. Electronic Sources

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

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

ALL data elements are in defined fields in electronic claims

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For <u>maintenance of endorsement</u>, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

N/A

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card. Attachment:

3c. Data Collection Strategy

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

3c.1. <u>Required for maintenance of endorsement.</u> Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues. <u>IF instrument-based</u>, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

Data collection is accomplished via Medicare Claims and CROWNWeb, a web-based and electronic batch submission platform maintained and operated by CMS contractors.

Measures reported on DFC are reviewed on a regular basis by dialysis facility providers. Review of comments and questions received in the past 3 years for SRR showed only rare instances of concern expressed about inaccurate or missing data.

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

4. Usability and Use

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

4a. Accountability and Transparency

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

4.1. Current and Planned Use

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

Specific Plan for Use	Current Use (for current use provide URL)
Regulatory and Accreditation Programs	Public Reporting
	Dialysis Facility Compare
Quality Improvement (Internal to the specific organization)	https://www.medicare.gov/dialysisfacilitycompare/
	Payment Program
	ESRD QIP
	https://www.qualitynet.org/esrd/esrdqip

4a1.1 For each CURRENT use, checked above (update for maintenance of endorsement), provide:

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

DFC:

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

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 10 patient years at risk (due to public reporting requirements). For the most recent update to Dialysis Facility Compare January 2020), 7,578 facilities had data reported on DFC.

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

QIP:

Purpose: The ESRD QIP will reduce payments to ESRD facilities that do not meet or exceed certain performance standards. The measure was added to the program for PY2017.

Geographic area: United States

Number of accountable entities: All Medicare-certified dialysis facilities that are eligible for the measure, and have at least 10 patient years at risk (due to public reporting requirements). For the most recent QIP report that is publically available (PY 2020), this was 7,420 facilities.

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

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?) N/A

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*) N/A

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

Results of this measure are currently reported on Dialysis Facility Compare and in the ESRD Quality Incentive Program. All Medicare-certified dialysis facilities are eligible for reporting in both programs (approximately 7,000 dialysis facilities). Each program has a helpdesk and supporting documentation available to assist with interpretation of the measure results.

The measure developer (UM-KECC) produces and distributes the DFC data under contract with CMS. Other CMS contractors calculate and distribute the ESRD QIP measure results.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

For DFC, the results are first reported to facilities via a closed preview period, where facilities can review their data prior to each of the quarterly updates of the public facing Dialysis Facility Compare website. These preview reports are posted on dialysisdata.org, where facilities can also find a detailed Guide to the Quarterly Dialysis Facility Compare Reports and other supporting documentation. Facilities can submit comments/questions about their results at any time, and can request patient lists for their facilities during the specified preview periods.

For the ESRD QIP, results are first reported to facilities via closed preview period on an annual basis; facilities can review their data prior to the results becoming public at the end of the calendar year. These preview reports are posted on qualitynet.org, where facilities can also find supporting documentation and can submit comments/questions about their results.

A measures manual that describes the calculations for both of these programs in detail is published on the CMS website: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/06_MeasuringQuality.html

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

For DFC, feedback can be provided any time through contacting the dialysisdata.org helpdesk. Preview periods allow for specific times for facilities to review and comment on measure calculations, and provide an opportunity to request a patient list.

For the ESRD QIP, feedback can be provided any time through contacting the QIP helpdesk. Preview periods allow for specific times for facilities review and comment on measure calculations. Comments can also be submitted in response to the Notice of Proposed Rulemaking for each QIP payment year.

4a2.2.2. Summarize the feedback obtained from those being measured.

DFC:

Comments received during DFC preview periods tend to be technical in nature, asking for clarification on how the SRR is calculated for particular facilities, including questions about patient assignment and application of exclusion criteria.

QIP:

We reviewed the public comments that were addressed in the ESRD QIP Final Rules (FRs) that have been published since the last endorsement (PY2017 – PY2022, described below). Note that since UM-KECC is not the contractor responsible for the ESRD Quality Incentive Program, we do not have access to the detailed comments that are submitted during the annual preview period for that program.

4a2.2.3. Summarize the feedback obtained from other users

QIP: Since the SRR was first proposed in the PY 2017 proposed rule, commenters raised issues related to additional risk adjustment for SDS factors or clinical factors, and question whether the outcome of the measure was attributable to the dialysis facility. Both of these issues are addressed in our submission. Commenters also echoed the concerns raised about the measure's reliability, based on the measure's calculated IUR.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not. As part of our Comprehensive Review of the measure, we have carefully considered the public comments and other feedback summarized above. We have significantly revised the approach to co-morbidity risk adjustment in response to comments, utilizing CCS condition categories rather than CMS HCC groupers in our modeling of expected results. In addition, we utilized a stepwise selection technique for inclusion of co-morbidity categories, creating an objective,

empirically-driven approach to co-morbidity adjustment. We have not included adjustments for sociodemographic variables for the reasons described in Section 2b3.4b in the testing results for this submission (see Testing Form). No additional changes to the measure were made in response to the reliability concern. However, we have included additional information about our assessment of the measure's reliability in the form of additional testing and reporting of the Profile IUR (PIUR), a new approach for measuring reliability that is based on the ability of the measure to consistently flag outliers and that emphasizes more the ability of the measure to identify facilities whose outcomes are extreme.

Improvement

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

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

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

Our analyses of the entire US Medicare chronic dialysis population demonstrate little or no improvement in the unadjusted readmission rate (readmissions/index hospitalization) over calendar years 2016-2018. In addition, we developed a three-year model of SRR (2016-2018) in order to determine whether there was a trend in the fully risk-adjusted SRR over that time period. This comparison also failed to demonstrate improvement in the several years since SRR was first implemented in Medicare value-based and public reporting programs.

The failure to demonstrate improvement can be interpreted in at least two ways. First, dialysis facilities might not be able to sufficiently influence the readmission rate for this population through expected coordination of care. However, the ongoing Comprehensive ESRD Care Initiative demonstration project has recently shown significant improvement in readmission after hospitalization, utilizing a modified SRR outcome metric and sophisticated Difference-in-Difference methodology to compare CECI participants to Medicare chronic dialysis patients receiving traditional care. (Marrufo, et al, 2019) The CECI project intervention began in October 2015 and results were reported over the two subsequent study years. The CECI preliminary results demonstrate the potential to reduce readmissions when dialysis facilities and nephrologists are incentivized to work in coordination to address this important quality initiative.

Alternatively, failure of readmission rates to decline after introduction of SRR may be a spurious finding. Readmission rates may have been influenced by concomitant changes in the hospital utilization in the chronic dialysis population, confounding the ability to measure real improvement in care coordination and readmission avoidance. This measure is potentially sensitive to changes in hospitalization patterns because its denominator is based on index hospitalizations, not population size. In fact, we have shown that risk adjusted hospitalization, but not unadjusted hospitalization rates have declined over the years 2016-2018. Specifically, the risk adjusted hospitalization rate for 2016 decreased by 2.7% compared to 2015 (p-value <0.0001). Subsequent years had a larger decrease in the hospitalization rate compared to 2015 at 6.8% lower for 2017 and about 5.7% lower for 2018 (p-value<0.0001 for both) compared to 2015. While the rate increased slightly for 2018 compared to 2017, this is likely due to random variation. The discrepancy between raw and risk-adjusted hospitalization in this population suggests that recently hospitalized dialysis patients may have relatively more medical complexity compared to those hospitalized in the early years of the decade when the SRR was first developed and tested. If true, then we might expect an increased readmission rate in the target population. Absence of increased readmissions in an observation period where sicker, more complicated patients are being hospitalized implies some relative beneficial effect of the measure, but the results are not sufficiently robust to unambiguously demonstrate improvement over time.

Reference

Marrufo G, Negrusa B, Ullman D, Hirth R, Messana J, Maughan B, Nelson J, Lindsey N, Gregory D, Svoboda R, Melin C, Chung A, Dahlerus C, Nahra T, Jiao A, McKeithen K, and Gilfix Z. Comprehensive End-Stage Renal Disease Care (CEC) Model. Performance Year 2 Annual Evaluation Report. Prepared for: Centers for Medicare & Medicaid Services. September 2019. https://innovation.cms.gov/Files/reports/cec-annrpt-py2.pdf

4b2. Unintended Consequences

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

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients. None

4b2.2. Please explain any unexpected benefits from implementation of this measure. None

5. Comparison to Related or Competing Measures

If a measure meets the above criteria <u>and</u> there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

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

Yes

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

0369 : Standardized Mortality Ratio for Dialysis Facilities

1463 : Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

1789 : Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)

2510 : Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM)

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

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

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

Are the measure specifications harmonized to the extent possible? No

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

SRR is harmonized with the Standardized Hospitalization Ratio for Admissions (NQF #1463) and Standardized Mortality Ratio (NQF #0369) currently undergoing measure maintenance. The SRR applies to the same population—Medicarecovered ESRD patients—as SHR and SMR. SRR, SMR, and SHR include Medicare Advantage patients as they constitute a growing population of ESRD beneficiaries (approaching 20%); both SRR and SHR include an indicator accounting for the proportion of Medicare Advantage coverage in order to minimize potential bias due to incomplete comorbidity ascertainment for MA patients. SRR, SHR, and SMR all restrict to inpatient claims for comorbidity risk adjustment and all measures adjust for a similar set of patient characteristics as the SRR and utilize fixed effects in their modeling approach. However, SRR adjusts for a different set of comorbidities that are associated with a high risk of readmission. There are several NQF endorsed measures that share the same focus with SRR but target different patient populations and/or care settings. The proposed SRR has the same measure focus—unplanned 30-day readmissions—as CMS' Hospital-Wide All-Cause Readmission Rate (NQF #1789), and the Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNF; NQF #2510). SRR is harmonized with both the HWR and SNF measures in restricting to the use of inpatient Medicare claims for comorbidity risk adjustment, and exclusion of planned readmissions. There are several differences between the SRR and the existing CMS HWR and SNF measures. Some of the differences are intended to account for unique features of the ESRD chronic dialysis population: Inclusion/Exclusion 1) SRR includes patients with incomplete claims history from the prior year. We do this to allow capture of incident ESRD patients that may not have a complete year of Medicare coverage; 2) SRR includes Medicare Advantage patients (approaching 20% of ESRD dialysis patients) while HWR and SNF are restricted to Medicare FFS patients with Part A only; 3) only SRR excludes discharges that follow a patient's 12th admission in the year; 4) SRR excludes from the numerator planned readmissions that include a diagnosis of "fluid and electrolyte disorders" (CCS 55) that meet other criteria for planned readmissions (see Appendix). Risk Adjustment 1) SRR does not adjust for comorbidities that are highly prevalent in the ESRD population, such as acute renal failure, dialysis status, kidney transplant, fluid/electrolyte disorders, and iron deficiency 2) SRR additionally adjusts for diagnoses (grouped by the Clinical Classification Software [CCS] method) that are relatively rare but have a high risk of 30-day readmission in the ESRD population; 3) SRR adjusts for length of hospital stay, diabetes as the primary cause of ESRD, time on dialysis, and sex; 4) only SRR includes an indicator for Medicare Advantage coverage at time of index discharge; (5) SRR adjusts for comorbidities identified during the index hospitalization which were not present on admission whereas HWR does not. Additional differences between the SRR and SNF are 1) the SNF includes a different target population (though we recognize a notable proportion of ESRD dialysis patients reside in nursing homes); and 2) SNF includes readmissions within 1-day of discharge while SRR excludes readmissions within 3days of discharge.

5b. Competing Measures

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

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

N/A

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed. Attachment Attachment: 2496_Flowchart.pdf

Contact Information

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

Co.2 Point of Contact: Kimberly, Rawlings

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

Co.4 Point of Contact: Casey, Parrotte, parrotte@med.umich.edu, 734-763-6611-

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

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

The following TEP members served an advisory role to CMS during the development process:

Brady Augustine: Aggressive Analytics, Inc

Steven Brunelli, MD MSCE: Independent Consultant Paul Eggers, PhD (non-voting member): NIDDK, National Institutes of Health Stephen Jencks, MD MPH: Independent Consultant Richard Knight: American Association of Kidney Patients Christopher Lovell, RN MSN CNN: Dialysis Clinic, Inc Frank Maddux, MD FACP: Fresenius Medical Care Allen Nissenson, MD FACP FASN FNKF: DaVita, Inc Paul Palevsky, MD: University of Pittsburgh School of Medicine Sharon Perlman, MD: All Children's Hospital Daniel Weiner, MD MS: Tufts University School of Medicine Jay Wish, MD: University Hospitals Case Medical Center

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2014

Ad.3 Month and Year of most recent revision: 04, 2020

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

Ad.5 When is the next scheduled review/update for this measure? 04, 2021

Ad.6 Copyright statement:

Ad.7 Disclaimers:

Ad.8 Additional Information/Comments: