NATIONAL QUALITY FORUM

# Memo

**February 4, 2015**

**To**: Consensus Standards Approval Committee (CSAC)

**From**: NQF Staff

**Re**: Appeal for All-Cause Admissions and Readmissions Measure 2496

## Appeal for Measure #2496: Standardized Readmission Ratio (SRR) for Dialysis Facilities

In accordance with the NQF Consensus Development Process (CDP), the 17 measures recommended by the All-Cause Admissions and Readmissions Standing Committee were released for a 30-day appeals period. On January 28, 2015, the 30-day appeals period for the all-cause admission and readmission measures closed. NQF received an appeal for the following measure: Measure #2496: Standardized Readmission Ratio (SRR) for Dialysis Facilities developed by the Center for Medicare & Medicaid Services and the University of Michigan- Kidney Epidemiology Cost Center (CMS/UM-KECC). The appeal was submitted by the Renal Physicians Association (RPA).

Accompanying this memo are the following documents:

- RPA letter of appeal for Measure #2496
- Response to the appeal from the CMS/UM-KECC measure developers

### CSAC ACTION REQUIRED

The CSAC will review the letter of appeal, the response submitted by the developers, and this memo in consideration of the appeal. The CSAC will determine whether to uphold the NQF Executive Committee's endorsement decision or uphold the appeal for Measure #2496: Standardized Readmission Ratio (SRR) for Dialysis Facilities (CMS/UM-KECC).

## Background

Measure #2496 is a new submission to NQF and was developed under stewardship of the Centers of Medicare and Medicaid Services (CMS/UM-KECC) (see full measure specifications). During the Committee's review of this measure, there was strong agreement that this measure addresses a high impact area of measurement where there is a significant opportunity for improvement. However, some members of the Committee were concerned that the dialysis unit may not be the appropriate accountable entity for this measure, noting that dialysis units can not compel nephrologists to see patients immediately after acute care discharges. Others on the Committee argued that while the locus of accountability may not be the dialysis facility at present, this measure and improvement efforts tied to it might be the type of impetus needed to improve care for this vulnerable population. These members also noted that with patients

spending nine to 12 hours in these units during the week, more could be done to improve care processes for these patients.

The measure passed each of the criteria – importance to measure, scientific acceptability, usability, and feasibility. However, the Committee was unable to reach consensus on Overall Suitability for Endorsement. As such, the Committee agreed to revisit this measure after the 30-day Member and public comment period.

During the Member and public comment period, the measure received one supportive comment, arguing that this measure addresses an important issue given that there is substantial room for improvement in the care processes of dialysis units. The remaining comments raised concerns about various aspects of the measure, including the appropriateness of attributing readmissions to dialysis facilities, the temporal logic of the measure, and issues concerns related to risk adjustment, testing, and intended use of the measure (See Measure Summary Table). A full reading of the comments can be found here.

The Committee took a second vote on August 7, 2014 after reviewing all the comments that were received on this measure. The votes were tallied and again, the measure did not reach consensus (See Voting Comments).

NQF's Consensus Development Process dictates that when a Committee is unable to reach consensus on a measure, the measure will advance to NQF Member Voting. Thus the measure was subsequently advanced to a NQF Member vote which opened on September 10 and closed September 24, 2015. The voting results indicated a lack of support for the measure among certain stakeholders.

The voting results were presented to the CSAC during their October 2014 CSAC conference call. There, members of the CSAC requested that NQF staff undertake additional consensus-building for all of the measures under consideration in this project. On October 20, 2014, NQF held an All-Member Web-Meeting, inviting all member stakeholders to participate in a discussion about the measures under review. The call provided an opportunity for NQF Members to voice their concerns and provide feedback for the CSAC's consideration.

The CSAC convened again during their November 2014 Conference Call where they reviewed all of the Standing Committee's deliberations, particularly the supportive votes at the in-person meeting on the individual sub-criteria, the Member and public comments, Member voting results, and the all-Member call feedback, the CSAC moved to make an endorsement decision. While acknowledging the various concerns raised by stakeholders on this measure, the CSAC approved Measure #2496 for, and generally agreed that when this measure is used in conjunction with NQF-endorsed Measure #1463 - Standardized Hospitalization Ratio for Admissions, dialysis facilities and hospitals would be incentivized to work together to coordinate care and reduce avoidable readmissions.

On December 22, 2014, NQF's Executive Committee unanimously ratified the CSAC's recommendation to endorse the slate of admission and readmission measures, *only* with the following conditions:

1. The Admissions/Readmissions Standing Committee will determine which measures must enter the trial period for consideration of socio-demographic factors.

2. NQF staff will work with Admissions/Readmissions Standing Committee and CMS to determine a plan for assessing potential unintended consequences, including a one-year look-back. The evaluation of unintended consequences will be initiated within approximately one year and possible changes to the measures based on these data will be discussed at that time.

NQF staff is in the process of developing plans to operationalize and address these conditions.

## Summary of Issues Raised in Appeal

NQF staff has reviewed the appeal and determined that the issues raised were based on NQF process issues, rather than measure-specific issues. The appellant's main concern is that the CSAC did not consider the Committee evaluation and Member voting results, which is the basis for their challenge of the endorsement decision. The appellants note that the CSAC voted to approve Measure #2496 despite its having reached only 14 percent approval among NQF Member Councils and 60 percent approval by the Standing Committee [see excerpt from the letter of appeal below].

> While the NQF failed to acknowledge the Standing Committee's strongly negative assessment, the NQF member vote also did not support the measure, as indicated in the NQF Member Voting results included in the November 12, 2014, CSAC memo.
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> The comment period and member voting comments reflect widespread consensus agreement that the measure should not move forward, echoing previous input received during the member comment period that ended in July. In fact, it was the only measure to receive comments from eight different stakeholder groups.
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> According to the CSAC Criteria for Decision-making document, the CSAC is instructed to do the following:
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> > Adequate consensus across stakeholders. The CSAC will consider concerns raised by councils and may conclude that additional efforts should be made to address these concerns before making an endorsement decision on the measure.
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> > Consensus development process concerns. The CSAC will consider process concerns raised during the CDP, such as insufficient attention to member comment or issues raised about committee composition.
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> The move to proceed with endorsing this measure in light of the comments provided by recognized content experts would indicate both a failure in transparency and failure to adhere to the standards of the CSAC.

**NQF Response:** NQF strives to ensure transparency throughout its consensus development process (CDP) and is dedicated to continuous process improvement. As part of our improvement efforts, the Consensus Task Force approved a new process for reaching consensus when the Standing Committee and the Membership have not done so. In cases where the Standing Committee has not reached consensus, the issue is resolved by putting the measures out for Member and public comment and having the Standing Committee re-vote after considering the comments.

The measure did not reach consensus on the final endorsement recommendation by the Standing Committee. However, it should be noted that the measure passed all four measure evaluation criteria at the Committee level, with majority High/Moderate ratings for the two must-pass criteria of Importance to Measure and Report and Scientific Acceptability of the Measure Properties.

**Voting Results for Measure #2496 during Standing Committee In-Person Meeting May 5-6, 2014**

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| Importance to Measure and Report | 1a. Evidence: Y-17; N-6;<br>1b. Performance Gap: H-15; M-8; L-0; I-0;<br>1c. Impact: H-20; M-3; L-0; I-0 |
| Scientific Acceptability of Measure Properties | 2a. Reliability: H-5; M-17; L-1; I-0<br>2b. Validity: H-1; M-16; L-7; I-0 |
| Feasibility | H-20; M-2; L-0; I-0 |
| Use and Usability | H-3; M-18; L-1; I-0 |

The appellant notes that the Committee did re-vote on the measure after adjudicating the comments. However, since the vote rendered was still considered "consensus not reached," the measure, per NQF's process, was advanced to a Member Vote. No measure was approved by the membership during member vote, and the voting results were shared with the CSAC. In an attempt to understand the consensus issues across stakeholders, the CSAC instructed NQF to move forward with additional consensus building, specifically, an all-Member web-meeting to better understand concerns surrounding these measures, as described in the background section above.

There were 134 participants on the web-meeting, representing Members from all eight councils. Based on polling of webinar participants, the highest priority issue was related to adjustment of the measures for sociodemographic factors. A summary of the call can be found in the November CSAC Memo, available on the NQF website.

The CSAC considered this feedback, as well as the information from the Committee deliberations, and the NQF Member and Public Comment Period, when making a final endorsement decision during their November 2014 meeting. Sixty-four (64) percent of CSAC members voted to approve Measure #2496 (9-Yes; 5-No).

Lastly, the appellants highlight a concern that the measure was ultimately endorsed by the CSAC without support from the membership or consensus from the Standing Committee. NQF defines consensus using the OMB Circular A-119 definition of "general agreement, but not necessarily

unanimity." In this case, the Committee was unable to reach consensus on whether the measure should be recommended for endorsement. As per the guidance from the Consensus Task Force, additional consensus building activities were undertaken. Specifically, the Standing Committee took an additional vote on the measure after considering public and member comment, the NQF Member council co-chairs were convened to further understand the issues related to the project, and the CSAC requested an all-member call prior to a final vote. Given these inputs, it is ultimately CSAC's role to review all measure recommendations by project Standing Committee, feedback by the membership from commenting, voting, and the all-member call, and make an endorsement decision. It is our understanding that the CSAC exercised their role responsibility appropriately, responsibly, and with transparency.

## Appendix A: Measure Evaluation Summary Table for NQF #2496

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

**2496 Standardized Readmission Ratio (SRR) for dialysis facilities**

Submission | Specifications

**Description**: The Standardized Readmission Ratio (SRR) is defined to be the ratio of the number of index discharges from acute care hospitals that resulted in an unplanned readmission to an acute care hospital within 30 days of discharge for Medicare-covered dialysis patients treated at a particular dialysis facility to the number of readmissions that would be expected given the discharging hospitals and the characteristics of the patients as well as the national norm for dialysis facilities. Note that in this document, "hospital" always refers to acute care hospital.

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

**Denominator Statement**: The expected number of unplanned readmissions in each facility, which is derived from a model that accounts for patient characteristics and discharging acute care hospitals.

**Exclusions**: Hospital discharges that:

- Are not live discharges
- Result in a patient dying within 30 days with no readmission
- Are against medical advice
- Include a primary diagnosis for cancer, mental health or rehabilitation
- Occur after a patient's 12th admission in the calendar year
- Are from a PPS-exempt cancer hospital
- Result in a transfer to another hospital on the same day

**Adjustment/Stratification**:

**Level of Analysis:** Facility

**Setting of Care:** Dialysis Facility

**Type of Measure**: Outcome

**Data Source**: Administrative claims

**Measure Steward**: Centers for Medicare and Medicaid Services

**STANDING COMMITTEE MEETING [05/05/2014-05/06/2014]**

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

(1a. Evidence, 1b. Performance Gap, 1c. High Impact)

1a. Evidence: **Y-17; N-6**; 1b. Performance Gap: **H-15**; **M-8**; **L-0**; **I-0;** 1c. Impact: **H-20**; **M-3**; **L-0**; **I-0**

Rationale:

- There was general agreement that this is a high impact area of measurement and there is opportunity for improvement, with the overall readmissions rate at approximately 30 percent and the readmissions rate for hemodialysis patients at approximately 36 percent.
- 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. Further, the member noted that NQF guidance regarding evidence for outcome measures was not strong enough, suggesting that the quality, quantity, and consistency of the evidence should be evaluated even for outcome measures.

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

**2496 Standardized Readmission Ratio (SRR) for dialysis facilities**

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

2a. Reliability: **H-5**; **M-17**; **L-1**; **I-0** 2b. Validity: **H-1**; **M-16**; **L-7**; **I-0**

Rationale:

- The Standing Committee discussed a number of threats to validity of the measure – mainly focusing on whether the dialysis unit was the accountable entity for 30-day readmissions back to acute care facilities.
    - One member argued that there are limited interventions a dialysis unit can implement that would influence this particular measure. This member noted that there are limited structures that allow the medical director or the governing body of the dialysis unit to compel nephrologists to see patients immediately after discharge from an acute care facility.
    - Other Committee members noted that while the locus of control may not be solely the dialysis facility, this measure and improvement efforts tied to it may be the type of impetus needed to improve care for this population. These members also noted that with patients spending nine to 12 hours in these units during the week, more could be done to improve care for these patients.

**3. Feasibility: H-11; M-9; L-4; I-0**

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

Rationale:

- The required data elements are routinely generated and used during care delivery and all data elements are in defined fields in electronic claims

**4. Use and Usability: H-3; M-11; L-10; I-0**

*(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)*

Rationale:

- Some members were concerned that the threats to validity would cause unintended consequences with the use of this measure in public reporting or accountability applications; however, there was limited evidence of unintended consequences identified.

**5. Related and Competing Measures**

- No related or competing measures noted.

**Standing Committee Recommendation for Endorsement**: **Y-8**; **N-12**

**6. Member and Public Comment**

- NQF received 10 post-evaluation comments regarding this measure. There was one supportive comment, arguing that this measure addresses an important high priority for measurement with sufficient room for improvement in the care processes of dialysis units. The remaining comments raised concern about the measure specifications, including the numerator specifications, denominator specifications, attribution, temporal logic, risk adjustment, testing, and intended use.

Numerator Specifications

- Commenters were concerned that the numerator definition relies on an accurate determination of planned admissions using codes from a non-ESRD population. Commenters encouraged validation of these codes in the ESRD population through examination of patient-level data from

**2496 Standardized Readmission Ratio (SRR) for dialysis facilities**

the CMS dry run.

- Commenters raised strong concern that the numerator of acute admissions does not consider ESRD-specific patient management – noting that this list of admissions should be tailored to include nephrology–related treatment. Commenters requested clarification on whether PD catheter placement or omentectomy, vascular access creation, or transfusion for a transfusion dependent patient fall is included in the measure.

Denominator Specifications

- Specifically, a commenter disagreed that the number of discharges should not be the determinant of the denominator, but rather the number of readmissions should be based on the total number of patients treated in a facility. Further, the commenter argued that the current measure is vulnerable to being skewed by the effect of one or two complex patients requiring frequent hospitalization.

Attribution

- Many commenters challenged the notion that dialysis facilities have the ability to affect readmissions. Commenters explained that dialysis facilities often do not receive any direct communication from the discharging hospital or facility for their patients, and are not supported to have coordinated presence in multiple hospitals. One commenter noted that a patient might be readmitted before ever being seen in the dialysis unit. This commenter noted that these readmissions are not actionable by the dialysis facility and should not be included in the measure. Further, commenters noted a lack of evidence showing that changes in a dialysis unit are the factors driving performance improvement.
- Additionally, a commenter noted that the majority of dialysis facilities do not have the resources for additional personnel, such as case managers, to improve care coordination between dialysis facilities and other health care providers. This commenter argued that dialysis facilities have a role in reducing all-cause readmissions; however, these facilities may not be the locus of control to manage the coordination required.
- Further, the commenter discussed that a dialysis unit has no control over a hospital's decision to re-admit a patient. The hospital physician decides whether or not to admit a patient, and many of these admissions have nothing to do with the nephrological issues being addressed by the dialysis facility and should also be excluded from the measure.
- Commenters also requested clarification on the frequency of admissions that occur prior to the first post-acute visit to a dialysis facility.

Exclusions

- Commenters requested clarification on how specific patient cohorts are handled in the measure. Additionally, a commenter requested clarification on how readmissions as a result of unsuccessful kidney transplants are handled in the 6 months following the transplant. Another commenter requested clarification on the rationale for excluding index hospitalizations after the patient's 12$^{th}$ admission in the calendar year. Further, this commenter requested clarification on why patients without complete claims histories and those who are readmitted within the 1-3 days after discharge are not excluded from the measure.

Risk Adjustment

- Commenters noted concern with the validity of the two-stage random effects risk-adjustment model. In particular, they requested clarification on how the measure is impacted by communities where there is only one major hospital and/or one major dialysis facility versus communities where there is many of one or both. The Commenters also noted that the risk

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adjustment model should reduce the number of variables to those that are clinically relevant.

- Further, another commenter noted that other comorbidities should be included in the risk adjustment model, including sickle cell trait, angiodysplasia, myelodysplasia, diverticular bleeding, and asthma. Additionally, the commenter suggested adjusting for nursing home status in the risk adjustment model. Commenters also requested clarification on whether "poisoning by nonmedical substances" includes ongoing/chronic alcohol or drug abuse and not just acute events.

Reliability and validity testing

- Commenters noted that the testing results demonstrating correlations between hospitalization and re-hospitalization do not enhance confidence in the measure. The correlations with access and *urea reduction ratio (*URR) are statistically significant but of very low magnitude, and the correlation with the *standardized mortality ratio* (SMR) also has a low magnitude. Another commenter noted that the area under the curve for the for the receiver operating characteristic (ROC) curve (C-statistic) for the multivariable model of <0.65 is quite poor and suggests that the model is inadequate.
- Commenters requested clarification on the minimum sample size required to provide a statistically stable value for the measure. They expressed concern that many individual dialysis facilities may be too small with wide confidence intervals, limiting the statistical validity of the results.

Intended use in the specific program (QIP) and its appropriateness

- Commenters expressed concern regarding the appropriateness of the intended use of this measure for the CMS ESRD *Quality Incentive Program (*QIP). Commenters argued that the measure should focus only on admissions that are actionable for dialysis facilities, making stratification by primary diagnosis for readmission important.

**Committee Response:** The Committee acknowledges the myriad of concerns raised by commenters during the comment period. Many of these issues raised by the commenters were discussed during the in-person meeting.

Some members of the Committee continue to be concerned with attributing the readmission to the dialysis unit. Members expressed concerns that it is difficult to hold a facility responsible for a readmission which occurs prior to the dialysis facilities' first post-discharge encounter with the patient. These members note that the rationale provided by the developer demonstrating the link to readmissions and dialysis unit care processes is limited.

However, the Committee acknowledges that while there is limited evidence of the link between processes undertaken by dialysis facilities and readmissions, there is ample evidence demonstrating improved readmissions in other populations with chronic disease and care that is provided in the outpatient setting. The Committee agrees that efforts to reduce unnecessary admissions and readmissions back to acute care facilities should be undertaken by all members of the health care delivery system. Many committee members agreed that this includes efforts undertaken by dialysis facilities in which patients spend a considerable amount of time.

**7. Consensus Standards Approval Committee (CSAC) Vote: Y-9; N-5**

**8. Board of Directors Vote: Ratified; December 22, 2014**

**9. Appeals**

## Appendix B: Comments Received on NQF #2496

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| Linda Keegan, Kidney Care Partners (KCP); Submitted by Dr. Lisa McGonigal, MD, MPH | Kidney Care Partners (KCP) greatly appreciates the opportunity to comment on the list of proposed measures for the All Cause Admissions and Readmissions Project, and commends NQF for instituting the continuous commenting policy, which facilitates greater stakeholder participation by permitting NQF Members and the public to provide input earlier and more thoughtfully.<br><br>As you know, KCP is a coalition of members of the kidney care community that serves as a forum for patient advocates, physicians, nurses, dialysis facilities, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with chronic kidney disease and End-Stage Renal Disease (ESRD).<br><br>One of the measures submitted to NQF for endorsement consideration was developed for use in the ESRD population and consequently is of particular interest to KCP. In reviewing this measure, the Centers for Medicare and Medicaid Services' (CMS) Standardized Unplanned 30-Day Readmission Ratio for Dialysis Facilities (SRR) (NQF #2496), we have identified several significant concerns and offer the following comments. We note that these same concerns were detailed in KCP's May 2013 comment letter to Arbor Research and CMS when the measures were under development;[1] to our knowledge, none of these issues were addressed.<br><br>I. KCP notes that, as specified, the SRR is inconsistent with CMS's Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (SMR) and Standardized Hospitalization Ratio for Admissions (SHR) measures. Specifically, these measures only include patients who have had ESRD for 90 days or more, and the proposed SRR measure does not appear to be harmonized in this respect. In our May 2013 comment letter to CMS, KCP requested clarification on why this difference is present and asked CMS to provide the data analysis on the implications of the difference. To date, these details have not been provided for stakeholder review, and KCP urges the All Cause Admissions and Readmissions Steering Committee to seek this information so as to allow for an appropriate evaluation of the underlying rationale for and aptness of this disparity. We stress that harmonization is of particular importance with the SHR, given the SRR and SHR are likely to be used in conjunction to obtain a complete picture of a facility's hospitalization use.<br><br>II. KCP notes that the SRR measure specifications submitted to NQF's Measure Applications Partnership (MAP) in November 2013 had an exclusion for index hospitalizations that occur after a patient's 6th readmission in the calendar year, which has now been revised to those that "occur after a patient's 12th readmission in the calendar year." KCP has requested that CMS explain the rationale behind this change. In particular, we are concerned about the impact of the revision on low-volume facilities, and believe it is imperative for CMS to report on the underlying distribution that led to the change in order to understand its implications as compared to the version submitted to the MAP. |

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| | III. KCP notes that CMS's Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio (NQF #1789) excludes patients who have incomplete claims history from the past year, but the proposed dialysis facility SRR does not. KCP requested in its May 2013 letter to CMS that it provide the data on readmission rates for patients who have a full year of claims versus those who do not, as well as data on the impact of such an exclusion on the sample size and performance gap. While this information has not to date been provided, we believe such data and analyses are necessary in order to understand why the dialysis measure is not and/or should not be harmonized with the hospital measure.<br><br>IV. CMS has incorporated numerous comorbidities into the SRR risk model, but KCP has recommended that in addition to sickle cell anemia, sickle cell trait also be included—as well as angiodysplasia, myelodysplasia, diverticular bleeding, and asthma. Likewise, we have suggested that the risk model also adjust for nursing home status, and have requested clarification on whether "poisoning by nonmedical substances" encompasses ongoing/chronic alcohol or drug abuse and not just acute events.<br><br>V. KCP believes the measure's risk model fails to adequately account for hospital-specific patterns and fails to adjust at all for physician-level admitting patterns—a particular concern because the decision to admit or readmit a patient is a physician decision. We note that geographic variability in this regard is well documented in other areas, and there is no reason to believe the situation is different for ESRD patients. Specifically, merely adjusting for the hospital as a random effects variable is insufficient. Recent research indicates that beyond a simple hospital ranking, broader regional and geographic variability persists and must be accounted for.<br><br>VI. KCP has recommended to CMS—and continues to strongly recommend—that the measure be limited to those readmissions that are related or actionable to ESRD, rather than the all-cause readmissions promulgated in the current specifications. Data from one KCP member revealed that approximately 45 percent of readmissions are not related or actionable to ESRD; moreover, only a subset of the 55 percent attributable ESRD admissions are same-cause-specific readmissions.<br><br>VII. In our May 2013 comment letter to CMS, KCP recommended that patients who are readmitted in the first 1-3 days after discharge be excluded from the measure. Data from two KCP members find that among patients who were rehospitalized within 30 days of the initial hospitalization in 2011, 11-17 percent were readmitted during this period—often even before the first outpatient dialysis encounter. Specifically, for one KCP member, 17 percent of patients were readmitted within 3 days post discharge, among whom only 35 percent of patients had been seen by the dialysis unit prior to the readmission. In other words, by an approximately 2:1 margin, rehospitalized dialysis patients had not been seen by the dialysis facility before readmission. Penalizing facilities for such situations is patently unreasonable. Further in this regard, during the first 8 days after discharge, up to 40 percent of patients were readmitted—again the dialysis center had had a limited number of encounters to intervene/affect quality of care.[2] Lastly, not |

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| | all discharges are to home and a significant number of patients are readmitted before they receive care from a dialysis facility. The measure should account for this.<br><br>VIII. Finally, CMS should provide data to demonstrate there is no bias of the SRR between rural and urban facilities; this is not simply adjusted for by the hospital as a random effect variable. We note that the distance of a patient's home relative to the outpatient facility and to the hospital likely influences their choices for care, and it likely further influences their utilization of care, particularly if there are symptoms that occur on non-dialysis days. The co-pay for transportation also may influence health utilization behavior. It is important for CMS to evaluate the impact of these factors on readmission rates for patients with ESRD and report why such factors should or should not be incorporated. We posit that billing data may shed light on how to evaluate these factors, yet they were not even considered.<br><br>Given the technical flaws and lack of validation elucidated above, KCP believes this measure should not be endorsed by NQF. We note that CMS has at its disposal the data to address a number of these issues—specifically the ability to understand the types of readmissions that dialysis patients experience, the length of time post-discharge when readmissions occur in relationship to when outpatient dialysis unit care resumes, the sites of service that patients are discharged to, and claims data related to physician admission/readmission for purposes of adjusting the model for this factor. Further, KCP is concerned with the approach and assumptions for the predictive model, which posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data. We strongly recommend a more evidence-based approach to this measure and reiterate our opposition to its advancement.<br><br>Thank you for your consideration of our comments and recommendations. Please do not hesitate to contact Lisa McGonigal, MD, MPH (203.298.0567or lmcgon@msn.com) if you have any questions.<br><br>Sincerely,<br>Linda DeRuvo-Keegan<br>Executive Director, KCP |
| Submitted by Mahesh Krishnan, MD MPH MBA FASN | DaVita Healthcare Partners treats nearly 170,000 ESRD patients in 2200 clinics. We are opposed to the suggested measure 2496, SRR for dialysis clinics. While we believe that readmissions are important in ESRD, the dialysis unit has limited ability to impact those outcomes for all causes. Based on 2011 Medicare Claims data, ESRD patients had an admission rate of 1.88 admits/pt/yr. The percentage of those admissions due to factors the dialysis unit can control were low, with 5% for vascular access infection, and 27% for ALL CV disease including fluid overload as well as CAD, AMI, and many others. The majority then of admissions and readmissions are due to other end organ manifestations of chronic disease, most of which are beyond the ability of the dialysis unit to manage. Further, 17% of patients had a readmission within 3 days post discharge, before even the first post discharge outpatient dialysis session. In our Special Needs Plan, a program with significantly more resources than a dialysis unit, we are able to affect all cause readmissions but only after expending considerable expense on IT and care coordination. The proposed |

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| | measure, intended to join a host of other measures in the Quality Incentive Program, would compete for resources amongst the 2% of payment withheld as part of that program. This is simply not feasible.<br><br>All cause readmission markers are appropriate for hospitals where care coordination and data are available. Dialysis units do not receive timely data, nor or hospitals required to provide data to dialysis units to coordinate care. Despite a large program to acquire every discharge summary for all of our patients, we were unable to obtain a significant amount of that data after a year following discharge, let alone within the few days required to coordinate care. This issue will be likely reflected in the comments to the dry run conducted by CMS and its contractor. There, our units were unable to ascertain the validity of the data given the lack of data mentioned above.<br><br>The statistical model used to risk adjust this measure has never been subjected to peer review. Recently the NQF noted that socioeconomic status may affect quality outcomes. This is not taken into account in the model. We have trended public data for Readmission rates currently distributed by KECC on behalf of CMS against census data for income a measure of socioeconomic status (SES). There dialysis units in high poverty locations were more likely to have higher readmit rates for each decile, while units in lower poverty locations were more likely to have lower rates.<br><br>We believe that this measure may better as a SES risk adjusted hospital measure not a dialysis measure. For dialysis, an SES risk adjusted and cause specific measure, such as one that includes fluid and vascular access infection would be more appropriate. |
| Robert Blaser, Renal Physicians Association; Submitted by Ms. Amy Beckrich | The Renal Physicians Association (RPA) does not support Standardized Readmission Ratio for Dialysis Facilities (Measure 2496). The RPA believes this measure is not appropriate for public reporting nor pay for performance for the following reasons:<br><br>1. There is a lack of evidence to support that changes in a dialysis unit processes are the primary factors driving performance on this measure. The single paper demonstrating that processes in the dialysis unit can reduce readmission rates (Chan et al) was quite small and has multiple methodologic flaws. Most importantly, there is a lack of plausibility that several of the specific intervention employed related to anemia management and vitamin D dosing were causally linked to reductions in re-hospitalization. This strongly violates the Chassin et al (NEJM) principle that there should be strong evidence for any measure used to assess quality.<br><br>Furthermore, the dialysis unit is the receiving facility, not the discharging facility, and the patient may be readmitted before ever being seen in the dialysis unit. The RPA is not aware of any robust analyses that have calculated what percentage of readmissions are attributable to dialysis unit processes as opposed to issues related to the discharging hospital. Therefore, the evidence available to support this measure is questionable.<br><br>2. 16% of readmissions occur before the first post-hospital discharge |

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| | outpatient dialysis treatment. As these readmissions are clearly not actionable by the dialysis facility, they should not be included in any measure. Furthermore, a dialysis unit has no control over a hospital's decision to re-admit a patient. The hospital physician decides whether or not to admit a patient, and many of these admissions have nothing to do with the nephrological issues being addressed by the dialysis facility and should therefore be excluded from the measure.<br><br>3. The discharging hospital often has no incentive to assure that the outpatient dialysis facility receives discharge information in a timely fashion. While sometimes it is the "home" hospital for the dialysis center, patients may be discharged from many hospitals to the dialysis center. The many to one relationship is not conducive to good communications. The TEP felt very strongly that any readmission metric should have adjusters for discharging hospital and for providers – the latter of which was not included in the measure as written.<br><br>4. The dialysis unit often doesn't receive any direct communication or discharge summary from the discharging hospital. This is a process that is not within the dialysis unit's ability to control.<br><br>5. The data as presented does not include a clear statement of the minimum number of admissions and readmissions that are required to provide a statistically stable value for the metric. The RPA is concerned the numbers at individual dialysis units will be too small to be meaningful and therefore may not meet validity standards for measures.<br><br>6. The area under the curve (AUC) for the for the receiver operating characteristic (ROC) curve (C-statistic) for the multivariable model of <0.65 is quite poor and suggests that the model is inadequate<br><br>7. KECC and CMS argue that the interdisciplinary team (IDT) has the power to prevent readmissions. In actuality, the IDT is not a team waiting at the center to immediately handle patient care; it is a virtual team which carries our assessments and plans of care.<br><br>RPA is the professional organization of nephrologists whose goals are to insure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease. |

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| Joseph Vassalotti, National Kidney Foundation; Submitted by Tonya Saffer, MPH | The National Kidney Foundation supports this measure conceptually, but we have suggestions for modification and concerns about its use.<br><br>Planned readmissions:<br><br>We recommend vascular access interventions meant to salvage an arteriovenous (AV) fistula or graft be considered in the sometimes planned category. Access problems such as aneurysms or stenosis can be detected on physical examination before the problem requires immediate intervention. Scheduling an an intervention electively can prevent ultimate thrombosis of or life-threatening hemorrhage from the access. If these interventions are uniformly considered unplanned, there could a disincentive to continue necessary elective interventions. This could cause an unnecessary vascular access replacement for the patient and potentially endanger patients by increasing catheter use if the access fails.<br><br>Modifications depending on intended use:<br><br>While an all readmissions cause measure for dialysis facilities makes sense for measurement in the Comprehensive ESRD Care (CEC) initiative because the ESRD Seamless Care Organization (ESCO) will receive incentives to address total patient care and partner with other health care providers, we believe that in its current form it is not appropriate for the QIP. A readmissions measure used in the QIP should focus only on admissions that are actionable for dialysis facilities, making stratification by primary diagnosis for readmission important. Examples include preventing readmissions for admissions related to congestive heart failure, fluid overload, hyperkalemia, and vascular access infection. Readmissions that occur within three days of discharge should also be excluded since in many cases the patient has not had any encounter with their dialysis facility. Addressing all-cause readmissions requires collaboration with other health care providers it is important for nephrology practitioners and dialysis facilities to play a role in this coordination, but taking on a leading role in coordination across all causes of admissions will require additional resources, such as case managers. The majority of dialysis facilities do not have resources for case managers. NKF believes that improved care coordination between dialysis facilities and other health care providers is necessary to improve outcomes. However other system changes need to be encouraged before dialysis facilities can coordinate patient care across healthcare settings.<br><br>We thank NQF for the opportunity to comment on the proposed measures |
| Mark Lukaszewski, The American Society of Nephrology (ASN); Submitted by Mr. Mark Lukaszewski | Please see submitted comment letter |
| Submitted by Dr. Lisa McGonigal, MD, MPH | Good afternoon. On March 20, Kidney Care Partners (KCP) electronically submitted comments on NQF measure # 2496, CMS's Standardized Unplanned Readmission Ratio for Dialysis Facilities (SRR). At that time I also sent a PDF version of our comment letter. |

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| AHIP; Submitted by Ms. Lauren M. McKown | This measure is not yet ready for wide-spread use as the accountability for management of ESRD patients is not well defined. This measure would be more appropriate in a bundled payment scenario than in the current CMS payment model. |
| Submitted by Dr. Franklin Maddux | Please see submitted comment letter |
| Submitted by Ms. Emma Kopleff, MPH | The Consumer-Purchaser Alliance urges the Committee to recognize the importance of this measure for consumers, families, and caregivers – as patients spend nine to twelve hours per week in dialysis facilities. Medicare patients undergoing dialysis treatments experience a 30% rate of 30-day unplanned readmissions, and therefore, we encourage the Committee to include this measure in order to address this high priority area.ii Not only are these readmissions a significant threat to health outcomes and costs, but they are also likely preventable. Multiple studies suggest that the implementation of certain care processes, including post-discharge assessments and changes in treatment at the dialysis facilities, may be associated with a decreased risk of admission. Although we understand the opinion voiced by Committee members that interventions by nephrologists may play a significant role in the risk of readmission, we believe that there is both sufficient room for improvement in the care processes in dialysis units and steps that dialysis facilities can take to prevent these readmissions. Lastly, "Use and Usability" does not require a passing vote in order for endorsement to be achieved. We would encourage the Committee to reexamine the consensus that was achieved in all "must pass" areas of the evaluation criteria and to reconsider this measure. |
| Submitted by Dr. Thomas James, III, MD | We agree that this measure is not yet ready for wide-spread use. The accountability for management of the ESRD patient has not been well defined. This measure would be more appropriate in a bundled payment scenario than in the current CMS payment model. |

## Appendix C: Comments Received during the Voting Period on NQF #2496

During the Member Vote period, several NQF Members submitted the following comments on Measure 2496.

**Voting Comments:**

- America's Health Insurance Plans: This measure is not yet ready for wide-spread use as the accountability for management of ESRD patients is not well defined. This measure would be more appropriate in a bundled payment scenario than in the current CMS payment model.
- Dialysis Patient Citizens: We cannot support endorsement of further readmission measures until the issue of socio-demographic status adjustment or peer grouping has been resolved by NQF and CMS. We also share the concerns raised about this specific measure-- that dialysis facilities lack sufficient control over hospital readmissions to be held accountable for this outcome.
- Akin Gump Strauss Hauer & Feld, LLP: Kidney Care Partners (KCP) has identified several significant concerns with Measure #2496 and offer the following comments.
  I. The SRR is inconsistent with CMSs Dialysis Facility Risk-Adjusted Standardized Mortality Ratio and Standardized Hospitalization Ratio for Admissions measures. These measures only include patients who have had ESRD for 90 days or more, and the SRR measure does not appear to be harmonized in this respect. Despite our May 2013 request for clarification on why this difference is present and for the data analysis on the implications of the difference, these details have not been provided for stakeholder review. We stress that harmonization is of particular importance with the SHR, given the SRR and SHR are likely to be used in conjunction to obtain a complete picture of a facility's hospitalization use.
  II. The SRR measure specifications submitted to NQF's Measure Applications Partnership in November 2013 had an exclusion for index hospitalizations that occur after a patient's 6th readmission in the calendar year, which has now been revised to those that occur after a patient's 12th readmission in the calendar year. KCP is concerned about the impact of the revision on low-volume facilities, and believe it is imperative for CMS to report on the underlying distribution that led to the change.
  III. CMS's Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio (NQF #1789) excludes patients who have incomplete claims history from the past year, but the proposed dialysis facility SRR does not.
  IV. The measure's risk model fails to adequately account for hospital-specific patterns and fails to adjust at all for physician-level admitting patterns a particular concern because the decision to admit or readmit a patient is a physician decision. Geographic variability in this regard is well documented in other areas, and there is no reason to believe the situation is different for ESRD patients.
  V. KCP strongly recommends that the measure be limited to those readmissions that are related or actionable to ESRD, rather than all-cause readmissions. Data from one KCP member revealed that approximately 45% of readmissions are not related or actionable to ESRD.
  VI. KCP recommends that patients who are readmitted in the first 1-3 days after discharge be excluded from the measure. Data from two KCP members find that among patients who were rehospitalized within 30 days of the initial hospitalization in 2011, 11-17% were readmitted during this period often even before the first outpatient dialysis encounter. By an approximately 2:1 margin, rehospitalized dialysis patients had not been seen by the

dialysis facility before readmission. Penalizing facilities for such situations is patently unreasonable. Further in this regard, during the first 8 days after discharge, up to 40% of patients were readmitted again the dialysis center had had a limited number of encounters to intervene/affect quality of care.

VII. Finally, CMS should provide data to demonstrate there is no bias of the SRR between rural and urban facilities; this is not simply adjusted for by the hospital as a random effect variable.

These points are further detailed in our previously submitted comments and in our accompanying letter to NQF. But in short, given the technical flaws and lack of validation elucidated above, KCP believes this measure should not be endorsed by NQF. We note that CMS has at its disposal the data to address a number of these issues. Further, KCP is concerned with the approach and assumptions for the predictive model, which posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data. We strongly recommend a more evidence-based approach to this measure and reiterate our opposition to its endorsement.

- American College of Medical Quality: The American College of Medical Quality (ACMQ) believes that all these measures should not be endorsed until there is consensus regarding an appropriate, standardized risk-adjustment methodology for Socio-Economic Status. Claims-based measures also to not take into account Present on Admission" status in risk adjustments."
- AAMC: The Association of American Medical Colleges (AAMC) has serious concerns with these readmissions measures. While the AAMC supports efforts to reduce all unplanned and adverse readmissions, we believe that these measures are seriously flawed and are not appropriate for use in either a reporting or pay-for-performance program. Most importantly, these measures have not been risk adjusted to account for sociodemographic status factors, which adversely affects hospitals that treat sicker and more vulnerable patients. The NQF is currently in the process of establishing a sociodemographic status (SDS) trial period, which is set to start in late December, 2014. The AAMC strongly urges NQF to delay action on this measure set until the conclusion of the SDS trial period, to allow steering committee members to make a more informed decision on the measures methodology. The AAMC also strongly believes that NQF should not move measures forward for a vote, where consensus was not reached among the Steering Committee members as is the case for three measures in the measure set.

# Response to Appeal of NQF #2496

We appreciate the opportunity to respond to the appeal request of the conditional endorsement of the Standardized Readmission Ratio (SRR) for dialysis facilities. While the appellant's main concerns are related to the NQF CSAC endorsement process, we wanted to briefly respond to a few of the underlying issues related to the review of the SRR measure.

## Methodological issues

In the course of the NQF review, we received many comments and criticisms that span all aspects of the SRR measure. These comments have been very helpful to us in making some refinements to the measure and in defining areas where further development is needed, as happens with all measures. We responded carefully and thoroughly to all of the comments during the public comment period prior to the August 6, 2014, meeting of the Steering Committee. (Note: For our detailed responses to the public comments that were submitted by the appellant with their complaint, please see the public comment and response documents that should be included as part of the background materials for this appeal review.)

A selection of comments and questions are summarized in italics, followed by our response. We are available to speak to these and our other responses at the committee's request.

- *Readmissions should be restricted to those that are related to ESRD or modifiable by facilities*. The 2012 CMS TEP concluded that an all-cause measure is appropriate for two main reasons. First, it was very difficult to establish agreeable and exhaustive conditions that are deemed modifiable by the facility. Second, an all-cause measure of readmission may be more valuable as it supports a paradigm of shared accountability, in which providers from different care settings are, as a group, accountable for the overall care of the patient

- *There is no adjustment for the nephrologist/physician who actually makes the readmission decision.* It is a CMS policy decision not to adjust for physician in the model for the following reasons. First, implementation and harmonization of such adjustment would affect many CMS measures and would raise many questions as to which physicians should be adjusted for. Second, the facilities have a legal obligation to oversee the quality of care provided by the interdisciplinary team, including physicians working in the dialysis unit.

- *The measure should exclude early readmissions in days 1 to 3 following discharge.* CMS made a policy decision to include the early readmissions in the measure because the measure is meant to encourage interaction between hospitals and facilities from the time of discharge. As specified, this measure encourages dialysis facilities to move up the time at which they first see patients after hospital discharge. In addition, excluding the first three days could allow gaming of the measure in moving up readmissions to the early time to avoid penalty. CMS conducted sensitivity analyses examining the change in SRR if the first three days post-discharge are dropped from the measure. The correlation between the two versions of the measure is 0.96. We also see a high degree of agreement (97.3%) between the two measures in terms of how facilities are classified under the measure (performing as expected, better than expected or worse than expected) Approximately 0.8% of dialysis facilities were classified as expected when early readmissions were included and worse than expected when early readmissions were removed; 0.7% of dialysis facilities moved in the other direction. These relatively small changes in facilities' performance on

readmission between the two versions of the measure provide empirical support for CMS' decision to consider early admissions in the SRR.

- *The denominator of this measure based on number of discharges is inappropriate.* There is in place a measure that evaluates admissions (SHR); this SHR is an important complement to the SRR in providing a full picture of dialysis facility management of hospitalization. Commenters have given artificial examples to show that the SRR could give very misleading results, in a case where the dialysis facility has a very low SHR. We have investigated this concern and find that there are no occurrences of situations where a facility has a better than expected admission rate and worse than expected readmission rate, as postulated in these examples. An abstract that thoroughly investigates the relationships between SHR and SRR was presented at the American Society of Nephrology Annual Meeting in November 2014.

- *The method of adjustment for hospital may disadvantage rural facilities with fewer choices of hospital.* We have carefully investigated this issue and, contrary to what has been conjectured by the commenters, the data show that rural facilities have lower adjusted readmission rates (median rural SRR=0.91; median non-rural SRR=1.02; 2012 data).

- *The model makes adjustment for too many variables and also does not adjust for certain comorbidities that would be appropriate.* The variables in the model have been selected on the basis of scientific and statistical relevance. Nonetheless, the model will be under regular review and additional adjustments will be made as appropriate – suggestions received will help guide these reviews. Based on earlier input, we did include an adjustment for high risk diagnoses empirically defined as diagnoses leading to readmission at least 40% of the time. This adjustment helps to avoid penalty for readmissions with these diagnoses.

- *The SRR has a c-statistic of less than 0.65 which indicates that the model is inadequate.* A 0.65 c-statistic is similar to that obtained by other readmission measures, some of which NQF reviewed and endorsed alongside the SRR. It should be noted that the c-statistic is a measure of model relative predictiveness and not of model adequacy; irrespective of its c-statistic, a model can be very useful in identifying facilities that have poor outcomes as compared to the national norm.

## NQF review process

The complaint registered by the appellant focuses on the belief that the NQF CSAC disregarded the opinion of the steering committee and membership when granting conditional endorsement to the SRR. While we cannot comment on the process or rationale behind the CSAC decision, we would like to reiterate our concerns with the steering committee review process, given that the appellants cite the "widespread consensus agreement that the measure should not move forward" based on the final steering committee and member votes.

We provide a brief summary of our main concerns below.

1. ***There was no consensus agreement that the measure should not move forward.*** As NQF emphasized at both the initial Steering Committee vote and following the public comment meeting in August, the votes received by the SRR indicated a lack of consensus around the measure, since it received between 40% and 60% of the counted votes in support of

endorsement. By this measure, we believe the appellants' assertion inaccurately summarizes the deliberations of the Steering Committee.

2. ***Insufficient opportunity for developer response to measure issues and concerns raised by Steering Committee.*** During the in-person meeting and subsequent public comment discussion, the lead workgroup discussant for the SRR measure provided extensive comments without sufficient opportunity for developer response. This was not observed in the course of the review and deliberation for the other measures.
3. ***Lack of feedback on committee concerns prior to the public comment meeting on August 6, 2014.*** There were no proposed committee responses in the memo that accompanied the materials for the public comment meeting. We are concerned that our comment responses did not receive the proper attention of the committee, especially since the final vote took place immediately after the comment call.
4. ***Lack of preparation for discussion of the SRR.*** The workgroup lead discussant for the SRR was not properly prepared for the discussion of public comments that took place on August 6, 2014. Specifically, he had not read the carefully constructed and informative responses provided by UM-KECC to each public comment. The lead discussant was then allowed time to express his detailed views on all aspects of the measure, without apparently having reviewed the responses provided by UM-KECC. More importantly, the discussion did not recognize the responses addressing those public comments.
5. ***Lack of rationale for committee votes.*** Throughout the review process, rationale was not provided for either of the two committee votes (both of which resulted in "consensus not reached" status).

We would also like to note that while the vote of the NQF membership was negative for all of the readmission measures, the main concern raised by the membership (adjustment for sociodemographic status) has been appropriately mitigated by the conditional endorsement status that was granted to the measures by the CSAC. CMS has recommended that the SRR be included in the SDS trial and we expect that the steering committee will concur with this recommendation.