



December 22, 2014

Christine Cassel, MD
President and CEO
National Quality Forum
1030 15th St NW, Suite 800
Washington, DC 20005

RE: Appeal of Measure 2496 - Standardized Readmission Ratio (SRR) for Dialysis Facilities

Dear Dr. Cassel:

Pursuant to the National Quality Forum's (NQF) Consensus Development Process, RPA and the organizations listed below formally appeal the Consensus Standards Approval Committee's (CSAC) decision on Measure 2496, the Standardized Readmission Ratio for Dialysis Facilities. We are highly concerned about the apparent overriding of both the Standing Committee and NQF member vote in regard to said measure, part of the All-Cause Admissions and Readmissions Measures set. The RPA has served as the lead nephrology organization for physician performance measure development.

The undersigned organizations appreciate the process by which proposed measures are evaluated during the NQF Consensus Development Process and recognize the need for a careful and deliberate process, especially during the development of the national voluntary consensus standards.

The undersigned organizations strongly support the concept of hospital admissions and readmissions measures for dialysis facilities and believe such measures have great potential for improving patient care. Hospital admissions among ESRD patients result in significant societal and economic burdens and have a negative effect on patients' well-being, quality of life, and overall mortality. Efforts to reduce the high rate of hospital readmissions among the dialysis patient populations are crucially important. However, as noted in the September 10, 2014, NQF draft report on the All-Cause Admissions and Readmissions Measures, the All-Cause Admissions and Readmissions Standing Committee failed to reach consensus on this, and two other measures.

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. CMS plans to use this measure for public reporting. 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 (see Appendix A). **After adjudicating the comments, the Committee took a second vote on this measure and again failed to reach consensus.**[emphasis added] This measure, along with the other measures on which consensus was not reached, will be released for a NQF member vote, which will take place September 10-24, 2014. The voting results will be shared with the Consensus Standards Approval Committee (CSAC), which will make the final endorsement decision.

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 November 12, 2014, CSAC memo:

- All Councils: 37%
- Percentage of councils approving (>60%): 14%
- Average council percentage approval: 29%

The comment period [Appendix A] and member voting comments [Appendix B] 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.

According to the CSAC Criteria for Decision-making document, the CSAC is instructed to do the following:

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.

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.

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.

We appreciate NQF's move toward Standing Committees, which appears to have reduced the endorsement cycle for the topics addressed and led to a more consistent endorsement process. Still, feedback from our member experts suggests that for some measures the endorsement cycle – from submission to final decision – is longer than the seven-months NQF has described to its membership. We believe that volunteer, multi-stakeholder committees are the central component to the endorsement process, and the success of the consensus development process projects is due in large part to the expertise and participation of its committee members. However, disregarding the extensive and agreed upon input of Standing Committee members and moving forward with non-consensus measures ignores their knowledge and disinclines them from a desire to devote precious volunteer hours to continue participation in NQF activities. The decision to move forward with this measure in the face of and despite the void in consensus compromises the credibility of the process as well as that of the NQF.

We urge NQF to seriously consider how its recent actions to disregard the expert advice provided will impact the measure review and endorsement process moving forward, as it currently appears to simply be 'going through the motions.'

We sincerely hope NQF Board of Directors will reconsider the CSAC's recent decision with regard to Measure 2496 - Standardized Readmission Ratio (SRR) for Dialysis Facilities due to the serious concerns the nephrology community has raised with this measure. Thank you for your attention to our concerns. The RPA along with our sister societies and community organizations look forward to working with the NQF and other relevant health care stakeholder groups to improve the quality measure review and endorsement process to ultimately improve patient care.

Sincerely,

Renal Physicians Association
American Nephrology Nurses Association
American Society of Nephrology
American Society of Pediatric Nephrology
Dialysis Patient Citizens
Kidney Care Partners

Appendix A - Comments received 2/5/2014 through 07/11/2014

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:

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.

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.

2. 16% of readmissions occur before the first post-hospital discharge 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.

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.

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.

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.

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).

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.

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.

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.

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.

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.

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.

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.

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.

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 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.

All cause readmission markers are appropriate for hospitals where care coordination and data are available. Dialysis units do not receive timely data, nor are 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.

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.

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.

The National Kidney Foundation supports this measure conceptually, but we have suggestions for modification and concerns about its use.

Planned readmissions:

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 intervention electively can prevent ultimate thrombosis or life-threatening hemorrhage from the access. If these interventions are uniformly considered unplanned, there could be 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.

Modifications depending on intended use:

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.

We thank NQF for the opportunity to comment on the proposed measures.

The American Society of Nephrology (ASN), the world's leading organization of kidney health professionals, represents nearly 15,000 health professionals who are dedicated to treating and studying kidney disease and to improving the lives of patients affected by kidney disease. ASN is a not-for-profit organization dedicated to promoting excellence in the care of patients with kidney disease. Foremost among ASN's concerns is the preservation of equitable patient access to optimal quality dialysis care and related services regardless of socioeconomic status, geographic location, complexity of comorbid illness, or demographic characteristics. ASN is pleased to have the opportunity to provide comments on the National Quality Forum (NQF) # 2496, the Standardized Readmission Ratio (SRR) for dialysis facilities, and appreciates the ongoing efforts of NQF in improving the quality and efficiency of care for patients via the measure development process.

ASN strongly supports the concept of the proposed SRR for dialysis facilities and believes this measure has great potential for improving patient care. ASN is pleased to see that the steward has attempted to look at real time data in order to adjust the expected number of patients being readmitted in the denominator. However, the society has several questions and concerns regarding implementation of the proposed SRR measure and believes these concerns must be clarified before the measure is finalized. First, the society believes that there are several challenges in methodology and other questionable aspects of the measure that lack validity, which are described in more detail in this letter. Of greatest concern is defining the denominator by the number of discharges rather than by the total number of beneficiaries.

Metric Development Process

ASN was troubled to learn that the measure—in its current form—was not supported by the members on the Technical Expert Panel (TEP). The society is concerned that, ultimately, the convened TEP had little influence on or input into measure development.

Defining Hospitalization

The society believes that clarification is required regarding how bedded outpatients and observation admissions are counted in the SRR.

Opportunity to Affect Care

ASN believes it is important that the dialysis facility have the opportunity to impact readmission before being held accountable for readmission. Unlike the proposed ESCOs, where elements like hospital-based transition care coordinators are highly incentivized to reduce readmission, current dialysis facilities are not supported to have similar coordinators to have presence in multiple hospitals. Accordingly, if a discharged patient is readmitted prior to being seen at the dialysis facility, the facility would not have

had the opportunity to intervene to prevent the readmission.

This concern applies to both readmissions within 48 hours as well as to readmissions from other healthcare settings (for example, if patients are receiving dialysis at a rehabilitation center rather than at their home facility following hospital discharge when they are readmitted). Although ASN acknowledges that the model developed by He and colleagues attempts to adjust for hospital effects and could potentially account for some rapid readmissions, this model has substantial limitations based upon a number of assumptions (Lifetime Data Anal (2013) 19:490–512) and is inadequate to account for this issue. ASN notes that a measure that does not hold the dialysis unit accountable for rapid readmissions that take place before the facility had the opportunity to affect care, would have far greater validity than the proposed adjustment strategy (which is discussed further below).

Denominator Total

Similar to the decision made with access infections where the number of catheters (the major cause of access-related bacteremia) does not determine the denominator but rather the number of patients determines the denominator, ASN believes that the number of discharges should not be the determinant of the denominator, but rather that the number of readmissions should be based on the total number of patients treated in a facility. The society believes that this structure would be far more representative of overall quality of care and far less vulnerable to the effect that one or two complex patients could have on the SRR of an otherwise outstanding facility. The chair of the TEP charged with development of this measure (Dr. Stephen Jencks) emphatically raised this point during the meeting. Dr. Jencks felt that a metric that defined readmission rates based on discharges rather than census was fatally flawed. For example, a dialysis facility with 50 patients may include one patient who is readmitted repeatedly, while no one else is hospitalized. The facility's performance will be poor if the current analysis is implemented but in reality care is in reality excellent. Using number of discharges introduces instability in to the SRR, which is skewed by non-representative data.

Using discharges as the denominator requires implementation of both a Standardized Hospitalization Ratio (SHR) and an SRR (see prior work by Dr. Jencks and his colleagues). Dr. Jencks demonstrated that hospitalization and rehospitalization metrics are fairly redundant as facility interventions to reduce rehospitalization affect both metrics similarly, thereby accomplishing quality goals with a single metric. In theory it may be possible to evaluate accurately and report a facility's performance using a fusion of the SRR and SHR. However, the need to amalgamate two metrics to define quality as well as the mandate for public reporting of each individual metric performance makes a complicated fusion concept unrealistic and renders the proposed metric potentially misleading. This second comment further emphasizes ASN's overarching concern that an excessive number of metrics dilutes the importance of and therefore the attention to any single metric.

In sum, given the above, the currently proposed SRR is very vulnerable to being skewed by the readmission of one or two individual patients, making it a far less robust measure of true quality than is optimal. These flaws thereby severely limit the utility of the SRR as an accurate, stand-alone quality metric.

Denominator Adjustment

ASN is also concerned with a possible lack of validity with the methods behind the double random effects model (stage 1) and how this is impacted by communities where there is only one major hospital and/or one major dialysis facility versus communities where there are many of one or both. ASN believes this information must be addressed before finalization.

Similarly, the use of the less conservative fixed effects model, despite the statements made by He et al in their methods paper regarding difficulty identifying lower performing small facilities, appears inappropriate for the overall purpose of the measure given the assumptions required for this model. The society believes that in order to instill confidence and validity in the model, the measure must reduce the number of variables included and focus on more clinically plausible variables. For example, ASN suggests that BMI derived from the 2728 form should not be used. These data, despite having statistical significance, are essentially uninterpretable. Challenges include the heterogeneity of weight (wasting and anorexia, edema, etc) at the time of dialysis initiation, inaccuracy of data entry on the 2728 form, and lack of face validity for the association between BMI at dialysis initiation to rehospitalization potentially occurring years later. Several of the results in this model are unexpected, albeit not necessarily inaccurate, raising questions about depth of investigation into the statistical model. For example, a 75+ year-old individual fares better than a 25-45 year-old individual. Admittedly, this is a model of readmission, so there may be peculiarities, such that this result may reflect the semi-competing risk of death or unexplored interactions. Similarly, individuals treated with dialysis >6 years fare better than those treated for 3-6 years, who fare worse than those treated for 1-2 years. Additionally, ASN specifically questions whether there is a system in place for model refinement as coding accuracy, which will be encouraged by inclusion of these data in quality metrics, catches up with the 'risk factors'. Additionally, the society questions whether these terms would appear different if the denominator included all patients rather than discharges, as is discussed above.

With regard to the model itself, despite statements in the Measure Justification Form (MJF) that correlation between hospitalization and rehospitalization should be reassuring, these correlations, presented in 2b2.3. of the MJF, do not enhance confidence in the validity of the measure. Hospitalization is required for rehospitalization, so a poor correlation here is not possible. The correlations with access and URR are statistically significant but of very low magnitude, and the correlation with the SMR also has a low magnitude.

Finally, ASN is concerned about denominator adjustment, which is a very difficult undertaking. The list of comorbidities in the denominator might be too extensive, such that the metric may be adjusting away factors that are modifiable and therefore important. Concurrently, the models may be insufficiently adjusted based on coding habits and the absence of data on important characteristics influencing readmission including social, economic and education factors. A March 2014 memo from the NQF specifically commented on this concern in the general population. They state:

“There is a substantial body of evidence that sociodemographic factors influence a variety of patient outcomes and some processes. Two accountability measures in particular have brought this discussion to the forefront: Hospital-wide All-cause Unplanned Readmissions and Medicare Spending per Beneficiary Measure. NQF’s current criteria do not allow adjusting performance measures for sociodemographic factors, out of a desire to make disparities visible in order to motivate efforts to improve care for disadvantaged populations. Rather, NQF policy recommends that performance measures be stratified – or calculated separately -- by sociodemographic factors, e.g., income, race, education etc to make those differences visible.”

Inclusion of specific variables in any statistical model is a difficult decision, and ASN acknowledges that the influence of dialysis providers in determining the clinical role for these variables is of import and hopes that this was accounted for in the SRR development process.

Numerator Concerns

ASN is concerned that the numerator, which relies on accurate determination of planned admissions, uses codes from a non-ESRD population for determination. The society urges validation of these codes in the ESRD population, which could be achieved with detailed examination of samples of patient-level data from the dry run.

ASN is also greatly concerned that the types of admissions do not consider ESRD-specific patient management. Given that this metric addresses a very specific population, we suggest tailoring this list to include nephrology –related patient care measures. For example, where does PD catheter placement or omentectomy, vascular access creation, or transfusion for a transfusion dependent patient fall into on this list? Clarification regarding how observation/bedded outpatient status is handled may be helpful for better understanding this concern.

Transplantation

ASN believes that there needs to be clarification of how unsuccessful kidney transplants are handled in the 6 months following the transplant. It is ASN's belief that these admissions may not reflect dialysis facility quality; rather these reflect the transplant and transplant complications. Therefore these patients and readmissions should be excluded from the denominator and numerator, respectively. This is important so that the measure does not adversely affect patients' access to dialysis or discourage transplantation.

The society's members are dedicated to providing the highest quality care for patients treated with dialysis and are concerned that gains made in terms of access to care and quality of care are not undermined as another unintended consequence of a fully developed quality measure.

The society hopes that the recommendations it offers in this letter are helpful, and stands ready to discuss these comments. ASN welcomes the opportunity to continue to collaborate with NQF in further improving and refining this important quality measure.

Appendix B – NQF 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 CMS's 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.