ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

1510 H Street NW • Suite 800 • Washington, DC 20005
p 202.640.4660 • f 202.637.9793 • www.asn-online.org

June 24, 2014

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

Re: National Quality Forum (NQF) #: 2496—Standardized Readmission Ratio (SRR) for dialysis facilities.

Dear Dr. Cassel:

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 attemped 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 regardingimplementation 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.

- <u>Denominator Adjustment</u>
  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.

- <u>Numerator Concerns</u>
  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.

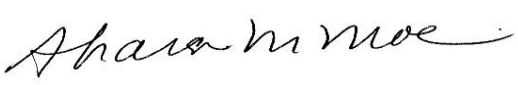
- Transplantation
  ASN believes that there needs to be clarification of how unsuccessful kidney transplants are handled in the 6 months following the transplant. It is ASN's belief that these admissions may not reflect dialysis facility quality; rather these reflect the transplant and transplant complications. 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.

Again, thank you for your time and consideration. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs at rmeyer@asn-online.org or at (202) 640-4659.

Sincerely,



Sharon M. Moe, MD
President, American Society of Nephrology