ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE
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January 12, 2016

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

RE: Draft Measures Application Partnership Pre-Rulemaking Input Report

Dear Dr. Cassel:

On behalf of the American Society of Nephrology (ASN), we thank you for the opportunity to provide comments on the National Quality Forum (NQF) Measures Application Partnership (MAP) Rulemaking Input Report. ASN is the world's leading organization of kidney health professionals, representing more than 15,000 physicians, scientists, nurses, and health professionals who strive to improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining patient access to optimal patient-centered quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

ASN appreciates the efforts of NQF, as well as those of the MAP, to identify the best available healthcare performance measures for use in specific applications. ASN would continue to encourage development and validation of meaningful outcome measures for people affected by kidney disease. ASN recommends that NQF continue to work with the greater kidney community in developing patient focused outcome measures that would benefit patient's lives.

The society submits the following comments on the proposed end-stage renal disease-related measures for your consideration.

End Stage Renal Disease Quality Incentive Program:

Standardized Hospitalization Ratio (SHR) – Modified
Standardized Mortality Ratio (SMR) – Modified
ASN supports both the SMR and SHR measure in concept; however ASN has several concerns with the current version. One major area of concern is related to CMS' Five Star program. In this context, it is important to view metrics in the manner in which they are currently being applied rather than as theoretical constructs. As of now, the SMR is used as a rigid point estimate without any accounting for potential variance. When a metric is used before endorsement, we have an interesting opportunity to comment on whether the current use is appropriate; in this case, endorsement of this metric would de facto endorse the current improper use of this particular measure as a rigid ordinal ranking system, which is counter to its design and its statistical qualities. Secondly, ASN would like to see some refinement of the denominator (expected) adjustments. Currently, the 1st stage model is adjusted for age, race, ethnicity, sex, diabetes, duration of ESRD, nursing home status, patient comorbidities at incidence, calendar

year and body mass index (BMI) at incidence. This should be updated to look at claims with a lag as is likely being done with more recently developed measures. This would also have the benefit of encouraging parsimony in measure methodology. Until these changes are made, ASN continues to have concerns with the measures as proposed. If these measures are endorsed, ASN urges NQF to comment on the appropriate use of these measures and the inappropriate use of ordinal ranking without accounting for statistical variance.

Standardized Readmission Ratio (SRR) for dialysis facilities
ASN 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.

Of greatest concern is defining the denominator by the number of discharges rather than by the total number of beneficiaries.

- Denominator Total
  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. Critically, as the ASN has outlined in detail in previous position statements, the SRR cannot be conceptualized independent of the SHR, reflecting that a small number of patients frequently readmitted can result in a facility appearing to be poor performing if that facility has a very low overall hospitalization rate. This point was made by the chairperson of the TEP charged with developing this measure when he withdrew his support for the measure.

Avoidance of Utilization of High Ultrafiltration Rate (≥ 13 ml/kg/hour)
ASN strongly supports this concept, but would recommend that NQF support the KCQA measures over the current CMS measure. While there are limitations with both of these measures, ASN feels that it is an important start to addressing one of the most important elements of dialysis care, volume management. As discussed by CMS in the 2015 ESRD Final Rule, we agree that gathering these data and understanding this measure are important prior to its inclusion as a performance measure attached to the QIP.

Proportion of Patients with Hypercalcemia (NQF #1454)
The society strongly opposes this measure and points out that there are sufficient data to show that it is not a valid performance measure (the EVOLVE trial assessed cinacalcet versus placebo in people with high normal and high serum calcium levels and found no significant difference in hard clinical outcomes in intention to treat analyses) and there are no data to show that it is a safety measure aside from trying to fit something into a safety measure column. Currently this measure is a weak measure of drivers of calcium levels (e.g., phosphate binder efficacy, dialysate calcium concentration, etc) and specifically supports the use of an expensive medication, cinacalcet, which has substantial gastrointestinal side effects, major cost implications and limited evidence supporting a benefit in hard outcomes. Given the exclusion of this agent from the bundle, dialysis facilities have no economic disincentive to the prescription of this agent, and therefore there is no cogent role for including a measure that financially disincentivizes cinacalcet non-use. Accordingly, NQF 1454 is not a patient-centered measure

as it encourages us to prescribe an agent that may be poorly tolerated, with twice as many participants in the cinacalcet group noting nausea and vomiting. We posit that cinacalcet will not be under prescribed regardless of the presence of this measure and therefore emphasize that a measure pushing cinacalcet prescription (as is described in the 2015 final rule as justification for its inclusion in the QIP) is unwarranted.

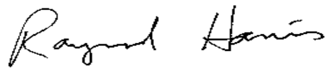
ESRD Vaccination: Full-Season Influenza Vaccination
ASN supports this measure and thanks NQF for including it in this year's MAP.

Measurement of Phosphorus Concentration
ASN supports this measure and thanks NQF for including it in this year's MAP.

ASN supports parsimony in measures. ASN believes that it is necessary and beneficial to have evidence-based metrics on important indicators of care quality for the non-dialysis chronic kidney disease population and the ESRD population. However, ASN also believes that redundant or discrepant measures, as well as measures that are not validated or do not address a care gap, may actually serve to threaten quality of care.

Again, thank you. If you have any questions about this letter or ASN's recommendations, please feel free to contact ASN Policy Associate, Mark Lukaszewski at 202-640-4635 or mlukaszewski@asn-online.org

Sincerely,



Raymond C. Harris MD, FASN
President