ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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National Quality Forum
601 13th Street NE
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Washington DC 20005

RE: Draft National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report

To whom it may concern:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of more than 12,000 physicians and scientists dedicated to promoting excellence in the care of patients with kidney disease, thank you for the opportunity to provide comment regarding the Draft National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report. Foremost among ASN's concerns is helping its members provide the highest quality of care possible to patients with kidney disease.

General comments

ASN supports the National Quality Forum's (NQF) commitment to improving the quality of life for patients with ESRD by identifying measures of the quality of care for ESRD that are suitable for public reporting and quality improvement programs. ASN was pleased to be represented on the NQF Steering Committee by ASN member Jeffrey Berns, MD, FASN, of the University of Pennsylvania School of Medicine. ASN appreciates the work of the Steering Committee and commends their efforts to identify Consensus Standards. The society thanks NQF for the opportunity to comment on the draft report at this time.

Comments on measures recommended

NQF recommended 11 measures for endorsement as voluntary consensus standards suitable for public reporting and quality improvement. ASN generally supports these recommendations, with the qualifications described below. However, the society wishes to note that at this time, scant high-quality evidence exists to support the majority of these measures. Developing new performance measures based on intermediate outcomes and retrospective observational studies will not necessarily improve care for patients with ESRD. Indeed, such measures could potentially lead to unintended adverse consequences or increased costs of care without improving meaningful, patient-centered outcomes. In the future, these measures should be replaced by new measures as scientifically validated performance targets are developed.

It is ASN's understanding that national voluntary consensus quality measures endorsed by NQF could potentially be used by the Centers for Medicare and Medicaid Services (CMS) as measures in the ESRD Quality Incentive Program (QIP) for value-based purchasing. Although based on the currently available evidence ASN does generally support the measures as

described above, the society has serious reservations about their suitability for a financially-incentivized measure due to the insufficiency of scientifically-validated evidence. Furthermore, ASN believes that it is imperative that any new measures CMS considers for the QIP must be subjected to rulemaking with a public comment period.

- **Dialysis Adequacy**

1418: Frequency of adequacy measurement for pediatric hemodialysis patients (CMS): Percentage of all pediatric (less than 18 years) patients receiving in-center hemodialysis (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.
ASN supports this measure.

1421: Method of adequacy measurement for pediatric hemodialysis patients (CMS): Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.
ASN supports this measure.

1423: Minimum spKt/V for pediatric hemodialysis patients (CMS): Percentage of all pediatric (less than 18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a pKt/Vgreater than or equal to 1.2.
ASN supports this measure.

- **Nutrition**

1425: Measurement of nPCR for pediatric hemodialysis patients (CMS) (Time-Limited): Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.
ASN supports this measure.

- **Anemia**

1424: Monthly hemoglobin measurement for pediatric patients (CMS): Percentage of all pediatric (less than 18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin.
ASN supports this measure.

1430: Lower limit of hemoglobin for pediatric patients (CMS): Percentage of pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients, with ESRD greater than or equal to 3 months, who have a mean hemoglobin less than 10 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation.
ASN supports this measure.

1433: Use of iron therapy for pediatric patients (CMS) (Time-Limited): Percentage of all pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin less than 11.0 g/dL and in whom serum ferritin concentration was less than 100 ng/ml and TSAT less than 20% who received IV iron or were prescribed oral iron within the following three months.
ASN supports this measure.

- **Fluid Management**

1438: Periodic assessment of post-dialysis weight by nephrologists (CMS) (Time-Limited): The proportion of patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month, irrespective of whether or not a change in post dialysis weight prescription was made.
ASN recognizes the importance of fluid management, but does not support this measure at the facility level. ASN suggests that this measure should be addressed at the clinician level. Furthermore, as currently written the specifications require a "prescription." ASN suggests that this be modified to an "assessment," as indicated in the description. A new prescription may not be necessary after an assessment.

- **Mineral Metabolism**

1454: Proportion of patients with hypercalcemia (CMS): Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL
ASN supports this measure.

- **Hospitalization**

1463: Standardized hospitalization ratio for admissions (CMS): Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.
ASN concurs that hospitalization is a crucial aspect of ESRD care to measure. However, as currently written, the measure encompasses all admissions. ASN suggests that the language be modified to specify a "Risk-adjusted standardized hospitalization ratio for admissions for dialysis access-related infections and fluid overload." If modified, ASN would support this measure.

- **Infection**

1460: National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC): Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.
ASN supports this measure.

Comments on measures not recommended

In general, ASN concurs with NQF's proposal not to recommend the remaining measures considered. ASN is aware, however, that some in the nephrology community have suggested that NQF reconsider measure 1427 "Adult dialysis patients—serum phosphorus greater than 6 mg/dl." (Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.) ASN recognizes that monitoring patients' serum phosphate levels is an important component of high-quality patient care.

However, based upon currently available evidence, ASN does not recommend that NQF reconsider measure 1427 "Adult dialysis patients—serum phosphorus greater than 6 mg/dl."

Importantly, serum phosphorus is a surrogate marker. Serum phosphorus control is a function of several components, and is strongly influenced by patient behavior—particularly with respect to diet. ASN is concerned that establishing a quality measure for serum phosphorus could potentially result in the unintended consequence of biasing some providers against caring for socioeconomically disadvantaged populations, as their nutritional options are more limited and they may not have access to the array of available phosphate binders. Additionally, blacks on

dialysis tend to have higher serum phosphorus concentrations compared with whites, in part owing to endogenous hyperphosphatemia from more severe secondary hyperparathyroidism. It would also be challenging to apply this measure for patients who dialyze at home.

Moreover, ASN believes that there is insufficient evidence that 6 mg/dl is in fact the most appropriate threshold, as well as insufficient evidence that lowering phosphorus translates into improved outcomes in terms of cardiovascular or bone disease outcomes or mortality. ASN also notes that there is a relatively low relative risk associated with hyperphosphatemia at the 6mg/dL level. Treating hyperphosphatemia involves expense, patient inconvenience, pill burden, dietary limitations, and drug adverse effects. In the absence of evidence, concern also exists that overly stringent nutritional restrictions for the control of serum phosphorus may contribute to the much-dreaded malnutrition that many patients on dialysis develop. In the absence of demonstrated benefit of treatment, ASN believes this measure is not a reasonable quality metric and should not be reconsidered by NQF. Serum phosphorus maintenance—as well as the other measures recommended for endorsement—are, however, areas ASN believes strongly would benefit from further investigation; randomized clinical trials as well as comparative effectiveness research would be of great value to the nephrology community.

Again, thank you for your time and consideration. The society is grateful for the opportunity to provide comment to NQF and would welcome the opportunity to contribute in any capacity in future quality measure selection or development. ASN would also be pleased to discuss these comments with the CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

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