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

January 13, 2015

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), 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 over 15,000 physicians, scientists, nurses, and health professionals who improve the lives of patients with kidney disease every day. ASN and the professionals it represents are committed to maintaining the integrity of the physician-patient relationship as well as simplifying patient access to optimal quality care, regardless of socioeconomic status, geographic location, or demographic characteristics.

ASN appreciates the efforts of NQF, as well as those of 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 work with the greater kidney community in developing patient focused outcome measures that would benefit patients' 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:

Measure E1919— Cultural Competency Implementation Measure and Measure X3716—Cultural Competency Reporting Measure:

ASN does not support Measure E1919 and therefore does not support Measure X3716. ASN believes that Measure E1919 is not adequately validated in dialysis facilities, which in general are far smaller than the institutions in which the

majority of testing occurred. While we agree that many of the preferred practices listed are useful for running medium and large-sized organizations, they are not appropriate for a facility level quality metric, where a small business model on the very local level is often followed. Critically, in the limited period of time provided for reviewing these proposed measures, we were unable to locate details of documentation of testing of this measure in dialysis facilities, although as best can be discerned from the measure specification, it was field tested at only 7 dialysis facilities in Texas only. Accordingly, we concur with the PAC/LTC Workgroup that voted 56% to 44% against support.

As stated in our prior comments, ASN notes that this type of measure is designed to improve patient experience; therefore, there is considerable overlap between the 'Preferred Practices' in NQF 1919 and the items surveyed in the ICH CAHPS. Additionally, many of the 'Preferred Practices' do not readily apply to the facility level, with these best implemented by organizations with fairly large staffs. For example, 'Preferred Practice 4' states: "*Establish an internal mechanism for developing strategies that involve using a committee of current diverse staff for recruitment, retention, and promotion of staff that reflect the community at all levels of the organization (including upper management).*" This, as written, clearly does not apply to a facility where there may be between 10 and 20 employees. Additional several of these elements are duplicative with the ESRD Conditions for Coverage (see tags V451, V451, V452, V453), while others (for example Preferred Practice 30) refer to following existing local, state and federal laws and regulations, a statement that should not require a QIP metric. Preferred Practice 32, on community outreach, states in the specifications that: "*Organizations should collaborate with community organizations, in particular for health education programs, where they can help to raise awareness about local healthcare services*." This implies a role for prevention in the community, which, although important, is currently not a goal of dialysis facilities and will not impact current patients. While NQF 1919 is well-intentioned, most of the 12 preferred practices are beyond the scope of individual dialysis facilities, which should, per their mission, be focused on delivering dialysis care. In sum, 1) this measure does not readily apply to many individual dialysis facilities, 2) elements which are applicable are generally already addressed within existing laws and the Conditions for Coverage, 3) elements within this measure that are applicable will be captured in ICH CAHPS which assesses patient impressions of whether competent care is occurring, and 4) this measure could substantially increase documentation demands and facility burdens with no evidence of a beneficial effect on dialysis patient outcomes.

Measure X2051— Delivered Dose of Dialysis Above Minimum -Composite Score:

ASN supports this measure in concept, and agrees that this measure should receive conditional support from NQF. As stated in our previous comment letter, ASN believes this measure should not use all three scores, but rather two separate scores for PD and HD or the composite. Using only the composite could help smaller home dialysis programs – as they could combine their PD and HHD

populations and possibly avoid falling below the threshold because of small numbers. Further evaluation is likely needed to determine the precise composition of the composite measure and the interplay among this measure and the existing dose of dialysis measures.

Measure X3718—Delivered Dose in Peritoneal Dialysis Above Minimum:

ASN applauds NQF's conditional support of this measure and supports its inclusion in this year's MAP.

Measure X3717—Delivered Dose of Hemodialysis Above Minimum:

ASN applauds NQF's conditional support of this measure and supports its inclusion in this year's MAP.

Measure E0419—Documentation of Current Medications in the Medical Record and Measure X3721—Medications Documentation Reporting:

ASN recognizes the critical importance of accurate medication reconciliation and supports this measure in concept, but agrees with the PAC/LTC Workgroup, who voted 56% to 44% against conditional support, that additional measure testing and development is needed prior to this measure being advanced. The society believes that defining when documentation or reconciliation should occur and then testing this timing strategy is essential for application to dialysis facilities. ASN agrees that identifying medications and medication changes at admission to the dialysis unit, and with each care setting transition is critical. However, ASN also notes that reconciliation is not necessary at each routine dialysis session, preferring serial regular reconciliation at an appropriate interval that should be specified and tested given the balance between resource allocation and benefits present in dialysis facilities. ASN would be pleased to work with measure stewards to develop and refine this measure, which addresses a critical patient safety issue.

Physician Quality Reporting System Measures:

Measure X3792—Controlling High Blood Pressure

ASN does not support this measure for applicability to dialysis patients but notes that it is likely appropriate for non-dialysis chronic kidney disease patients. ASN stresses that this distinction is important for appropriate application of this metric. Even though many patients undergoing dialysis have high blood pressure, it is not known at this time what the target blood pressure is that results in best health outcomes. While there is no evidence that higher blood pressure results in higher risk for adverse events, there is consistent evidence that dialysis patients with the lowest blood pressure have a highest risk for death. Moreover, there are many patients such as those with diabetes and orthostatic hypotension, in which trying to get blood pressure to < 140/90 mm Hg is very risky. For all these reasons, we strongly believe that this measure is inappropriate for patients undergoing maintenance dialysis.

Measure E2152—Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:

ASN does not support this measure and agrees with NQF regarding the measures' need to be fully developed before it is reconsidered.

Measure X3512—Hepatitis C: One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk and measure X3816—Hepatitis C: Appropriate Screening Follow-Up for Patients Identified with Hepatitis C Virus (HCV) Infection:

ASN agrees with NQF that measure X3512 and X3816 should be fully developed before these measures are reconsidered. ASN notes a discrepancy between these proposed measures (X3512 and X3816) and the current Conditions for Coverage, which, in 2008, specified an exemption for hepatitis C screening, since Medicare only covers diagnostic hepatitis C testing when indicated and does not cover general screening for hepatitis C. The CDC recommends assessing Hepatitis C serologies in order to detect an outbreak of Hepatitis C, not in order to treat Hepatitis C. If the intent of these proposed measures is to encourage treatment of Hepatitis C, as they seem to be, ASN suggests that this metric may be premature, pending further research into the efficacy, safety and utility of treatment of Hepatitis C in dialysis patients, particularly in those patients unlikely to receive kidney transplants and those without other evidence of liver disease.

Measure X3476—Diabetes: Hemoglobin A1c Overtreatment in the Elderly:

Given the difficulties with the accuracy of Hemoglobin A1c in individuals with advanced chronic kidney disease and, particularly, in those treated with dialysis, ASN does not support this measure and agrees with NQF that this measure should continue to be developed before it is reconsidered. There are substantial data showing that HbA1c underestimates glycemic control in the advanced kidney disease population, likely due to more rapid red blood cell turnover. Please see Chen et al, *Am J Kidney Dis* 2010 for non-dialysis CKD and Freedman et al, *Perit Dial Int* 2010 and Peacock et al, *Kidney Int* 2008 for dialysis patient data. Therefore, we have concerns about the validity of the measure in this population.

Measure X3283—Closing the Referral Loop -Critical Information Communicated with Request for Referral:

ASN does not support this process measure, and believes this measure would be very difficult to track. Given the recent inclusion in the ESRD Final Rule suggesting referrals be made from dialysis units for certain conditions, we note that facilities currently lack the capacity for electronic transmission of referrals through a common EMR.

Measure E0076—Optimal Vascular Care:

ASN supports this measure in concept for individuals with CKD not requiring dialysis but opposes inclusion of dialysis patients in this metric. ASN is concerned though that dialysis patients would be included in this metric as there

are no data supporting any benefits to patients achieving the proposed targets or from lipid-lowering medications. There are three large clinical trials that have failed to show any reduction in risk for death with lipid lowering therapies in patients undergoing dialysis. Consistent with these findings, expert groups such as KDIGO and KDOQI do not recommend routine testing and/or treatment for hyperlipidemia for patients undergoing dialysis.

Measure X3469—Cognitive Impairment Assessment among At-Risk Older Adults:

ASN supports this measure in concept, but believes this measure potentially should be applied to younger patients as well as older if including kidney failure patients. ASN notes that cognitive impairment patterns may be different in non-dialysis CKD and dialysis patients, and that cognitive performance may not be accurately assessed by Alzheimer's screening tools like the Mini-Mental State Examination, and ASN stresses that there needs to be validation of cognitive screening tests in the CKD populations in order for screening to be useful.

Measure X3468—Documentation of a Health Care Proxy for Patients with Cognitive Impairment:

ASN supports documentation of health care proxies for all individuals with advanced chronic diseases.

Measure X3729—Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:

ASN cannot support this measure as written as data does not support initiating statins in prevalent dialysis patients, agreeing with NQF that this measure should be fully developed before it is reconsidered. This is stated in the recent KDIGO clinical practice guideline and the US National Kidney Foundation KDOQI commentary on this guideline. ASN supports this measure for non-dialysis CKD patients, but feels strongly that viewing populations as homogenous in these measures is inappropriate, particularly when well-conducted randomized clinical trials have shown negative results.

Measure X3777—Documentation of Signed Opioid Treatment Agreement:

ASN supports this in concept, and understands that chronic pain is a concern for those with complex chronic disease. Patients on dialysis often have their opioid use managed by their primary care or non-dialysis care provider. The contract should be with the primary care provider or provider that manages the pain, not the dialysis facility or subspecialist.

Measure X3774—Evaluation or Interview for Risk of Opioid Misuse:

ASN supports this in concept, although believes that this should apply to the prescribing individual/practice/setting rather than to every setting in which the patient is seen.

Measure X3732—Adult Kidney Disease: Referral to Hospice:

ASN supports this in concept, although believes this measure must clearly define 'withdrawal' as well as define how inpatient (hospital level) vs outpatient and sub-acute facilities are accounted for in the denominator and numerator, respectively. We would be pleased to work with CMS to develop precise definitions for use in a measure like this.

Measure X3733—Pediatric Kidney Disease: Discussion of Care Planning:

ASN supports this concept, but does not support this as a concept measure as this is already required as a function of the Conditions for Coverage and worries that this measure may actually be less flexible than the CfCs when it comes to potentially complex family dynamics, particularly among older adolescents. As such, ASN agrees with NQF that this measure should be fully developed before it comes up for consideration.

Measure X3475—Substance Use Screening and Intervention Composite:

ASN does not support this measure and believes that this may be an appropriate measure as a metric in the primary care setting but is not suitable for dialysis facilities. As such, ASN agrees with NQF that this measure should be fully developed before it comes up for consideration.

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. The society observes that, under the Conditions for Coverage (CfC) system for dialysis units, states conduct detailed periodic inspections while CMS maintains well-delineated interpretive guidance. Critically, avoiding discrepancies with the CfCs and minimizing redundant regulations are important for efficiency, minimizing patient survey burden and is important for validity in achieving desired outcomes of measures. It is within these contrasts that we commented on the currently proposed measures.

Again, thank you. If you have any questions about this letter or ASN's recommendations, please feel free to contact ASN Manager of Policy and Government Affairs, Rachel N. Meyer, at 202-640-4659 or rmeyer@asn-online.org.

Sincerely,

John R. Sedor, MD, FASN
Public Policy Board Chair