ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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Gerald M. Shea
Interim President and Chief Executive Officer
National Quality Forum
15th Street, NW
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RE: Draft Measure Applications Partnership Pre-Rulemaking Input Report

Dear Mr. Shea:

Thank you for the opportunity to provide comments on the National Quality Forum (NQF) Measure Applications Partnership (MAP) Pre-Rulemaking Input Report. The American Society of Nephrology (ASN) represents more than 14,000 physicians, scientists, and other healthcare professionals dedicated to providing high-quality care to kidney patients and to developing cures for kidney diseases.

ASN and the professionals it represents are strongly committed to maintaining the integrity of the physician-patient relationship as well as to equitable patient access to optimal quality care regardless of socioeconomic status, geographic location, or demographic characteristics. ASN appreciates the efforts of NQF, as well as MAP, to identify the best available healthcare performance measures for use in specific applications. The society recognizes the importance of evidence-based clinical practice measurements in advancing the quality of care.

Overall, ASN recommends that MAP, NQF, and other entities proposing or implementing quality measures prioritize outcomes measures over process measures, and that any measures being considered should address a gap in care or a clear opportunity for improvement. Any process measures that are considered should be process interventions—such as using acetylsalicylic acid for presumed myocardial infarctions—rather than process monitoring—such as checking calcium levels monthly. Furthermore, any measure being considered for inclusion in a quality improvement initiative should already have been endorsed via a formal consensus-based process, such as the NQF process. Finally, ASN suggests that data collection should rely on claims and easily obtained clinical information that does not require extensive chart review or access to multiple data sources. Several of the proposed MAP measures would require complex data collection, a challenge that could have been considered and addressed in an NQF process in advance.

ASN is committed to participating in the consideration and selection of evidence-based quality measures related to kidney disease care and kindly submits the following specific comments on the measures related to end-stage renal disease for your consideration.

Adult Measures

Measure 2771: Percentage of adult (>= 18 years old) hemodialysis and peritoneal dialysis patients whose ESA dose is unchanged or increased when the hemoglobin value reaches or exceeds 11.0 g/dL.

ASN concurs with MAP's recommendation not to support measure 2771 at this time. A performance measure that requires a change in ESA dose based on a single laboratory value does not accurately reflect the care provided and does not consider patient-specific circumstances. ASN suggests that a more well-designed measure would examine the averages of data over the course of several months and allow for individualization of patient care. Furthermore, insufficient evidence exists to expect a reduction in ESA dose for every patient whose hemoglobin level exceeds 11.0 g/dL. Clinical trials indicated an increased risk for adverse events when the ESA was dosed to achieve target levels of 13.0 g/dL or higher.

Measure 2772: Percent of adult (>= 18 years old) hemodialysis and peritoneal dialysis patient months at a facility during the year for which a patient had a low achieved hemoglobin (<10 g/dL or missing), a low ESA dose (<75 units/kg/session of epoetin alpha, <0.2 mcg/kg/session of darbepoetin alpha, or missing), and was followed in the subsequent month by a red blood cell (RBC) transfusion. Exclusions: Receiving dialysis < 90 days, had < 6 sessions reported during the month, etc.

ASN concurs with MAP's recommendation not to support measure 2772. Currently, there is a lack of high-quality scientific evidence to support this measure and there is no scientific basis that a "low" ESA dose is the only determinant of need for transfusion, as the measure implies as written. Acute interceding illnesses, such as gastrointestinal bleeding and surgical procedures, can result in abrupt decreases in hemoglobin that may require blood transfusions unrelated to the quality of care provided in dialysis facilities. Furthermore, because the measure as written examines transfusions in the month after a low hemoglobin count or ESA dose, patients who receive a transfusion before the start of the next month (i.e. in the month that the low hemoglobin level is obtained) would not be identified by this measure as written. It is also important to recognize that nephrologists and dialysis providers have little control over most transfusions—a majority of transfusions are ordered by emergency room physicians, hospitalists, and other providers in in-patient settings. It is unclear whether this measure could be implemented in a way that distinguishes which provider type ordered the transfusions, risking unfairly penalizing dialysis units. Lastly, the meaning and implication of a "missing" hemoglobin or ESA dose is unclear.

Measure 1454: Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

ASN does not agree with MAP's recommendation to support Measure 1454. The only evidence that high serum calcium is associated with death risk is based on observational studies. Furthermore, what defines high serum calcium—and should be benchmarked—is not consistent across studies that have shown an association with death risk. There is little or no scientific basis of selecting a serum calcium concentration above 10.2 mg/dL as indicative of poor patient care or predictive of poor patient outcomes. It is also not clear that there is a performance gap in this area. Implementing Measure 1454 also creates the potential for 'cherry-picking' patients who are not likely to trigger this measure, jeopardizing access to care for certain patients without providing any clear overall population benefit.

Measure 0255: Percentage of adult (>= 18 years old) hemodialysis and peritoneal dialysis patients with serum phosphorus measured at least once within the month.

ASN does not agree with MAP's recommendation to support Measure 0225. Measure 0225 is a purely process-based measure, and it is not clear that there is a significant performance gap in this area. Therefore, it is unlikely that this measure would make a meaningful difference in patient outcomes and likely that it will add to the administrative burden and cost for dialysis facilities.

Measure 2059: Percentage of adult (>= 18 years old) hemodialysis and peritoneal dialysis patients with serum calcium measured at least once within the month.

ASN agrees with MAP's conclusion not to recommend this measure. Like Measures 1454 and 0255, there is a lack of evidence of a performance gap in care; this measure is, as with others, a process measure only that is unlikely to significantly improve care.

Measure 2775: This measure reports the percentage of adult hemodialysis and peritoneal dialysis patient-months in the following ranges of serum phosphorus: <3.5 mg/dL; 3.5-4.5 mg/dL; 4.6-5.5 mg/dL; 5.6-7.0 mg/dL; >7.0 mg/dL (The normal range for serum phosphorus is 2.5-4.1 mg/dL).

ASN agrees with MAP's recommendation not to support Measure 2775. The sole purpose of this measure appears to be to gather descriptive data on the distribution of serum phosphorus in dialysis facilities. The serum phosphorus ranges identified in the measure description are arbitrary and not based on any strong available scientific evidence: Variation exists in the available literature regarding the thresholds above which risk of mortality is elevated. Furthermore, there is no evidence from clinical trials that reducing elevated serum phosphorus levels has a tangible effect on any patient outcome.

Measure 1438: Proportion of patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month.

ASN does not agree with MAP's recommendation to support Measure 1438. Although monitoring fluid balance is important, there is no evidence that simply reporting the post dialysis (dry) weight was documented is associated with and leads to improved outcomes for patients. Documenting patients' post-dialysis (dry) weights could easily be re-prescribed monthly—even automatically via an electronic health record program—to comply with the metric without truly assessing the best fluid balance for the patient. Finally, ASN questions whether the measure description is correct: it appears the denominator includes all patients on dialysis instead of patients on dialysis during the specific month of the study.

Measure 1463: Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.

ASN agrees with MAP that this measure concept is promising but requires modification or further development before implementation is considered. Specifically, ASN is concerned about the limitations of risk adjustment for this measure. Centers for Medicare and Medicaid Services (CMS) Form 2728 is completed at the time of dialysis initiation, and hence cannot accurately reflect patient comorbidities at the time of a hospitalization that occurs remote in time from when the form was completed. There are also significant concerns about the accuracy of the 2728 form even at the time of dialysis initiation. Until such time as there is a mechanism in place to

use claims data or other means of concurrent assessment of comorbidities and hence risk of hospitalization, ASN does not support use of Measure 1463.

ASN is also concerned that this measure could lead to cherry-picking of healthier patients or patients with primary care physicians over patients without one, or patients with other less desirable characteristics such as a history of gastrointestinal bleeding or malignancy.

Measure 2132: Ratio of the number of index hospital discharges that resulted in a readmission within 30 days of discharge for Medicare-covered dialysis patients treated at a particular dialysis facility to the number of readmissions that would be expected given the discharging hospitals and the characteristics of the patients.

ASN supports the concept of Measure 2132 but has several concerns about the measure as proposed, detailed below. However, given that more than 30 percent of dialysis patients are readmitted within 30 days, ASN acknowledges that a well-designed hospital readmission metric has substantial merit.

- The CMS Technical Expert Panel convened to develop the proposed measure has not supported it.

- In order for a readmission to be attributable to a dialysis facility, there needs to have been an opportunity for the dialysis facility to affect care; for instance, if the patient comes to the dialysis facility one day after hospital discharge and requires readmission, this should not affect the dialysis facility as there was no opportunity for the facility to intervene.

- The modeling in the two-stage model may introduce biases, a concern that would need to be better explored before implementing this measure. For example, it is unclear how the model would perform in communities where there is only one major hospital and/or one major dialysis facility versus those where there are many of one or both.

- The list of adjusters may be too extensive, such that the potentially modifiable patient conditions that can be addressed to reduce readmissions may contribute too much.

- The potential for a single patient to count a maximum of 12 times in the denominator may be weighing an individual patient too much, potentially marginalizing access to care for high-risk patients.

- Body Mass Index (BMI) information on CMS Form 2728 should not be used. Given the heterogeneity of weight (wasting and anorexia, edema, etc.) at the time of dialysis initiation, interpretation is difficult. And similar to the Standardized Hospitalization Ratio for Admissions, there is no face validity to the concept that baseline BMI based on Form 2728 is relevant to a readmission several years later, even if statistically significant.

- The adjuster for functional disability and quadriplegia are lumped together, although they are not comparable clinical characteristics.

- The metric needs to specify the definition of “acute care hospitals.”

- The term “Planned Admissions” needs to be tailored to the dialysis population. For a dialysis measure, vascular access or peritoneal access placement/creation are typically

planned and should be counted as such. In reviewing the Methodology from CMS's Hospital-Wide Readmission Measure (May 2012 Report) that resulted in the definition of "planned" used in this metric, there was very little internal medicine input and no apparent nephrology input. There is a mention in this document that "fluid and electrolyte disorders" disqualify an admission from being planned, and this could be problematic for dialysis patients as this is a common code that is used. Another code that can be misused is "acute and unspecified renal failure," while a code that may affect vascular access creation is 237—complication of device, implant or graft (e.g., a graft clotted and a patient therefore has a new graft or fistula created). Additional review is needed to make sure that these general medicine measures can be accurately applied to the dialysis population.

- In the presentation of draft data from 2009, there are some facilities that are marked outliers. Before any codification of a metric, these positive and negative outliers need to be examined as they may provide clues to measure validity and potential fixes.

Measure 0369: Risk-adjusted standardized mortality ratio for dialysis facility patients.

MAP supports use of Measure 0369; ASN also supports the concept of Measure 0369 but is concerned about the data the measure uses for risk adjustment, which is unspecified. As detailed above, data on CMS Form 2728 are not a true reflection of a patient's co-morbid conditions at the time of death and inappropriate for use as a risk adjuster. Dialysis providers would be penalized for highly complex patients with multiple significant co-morbid diseases. Similar to Measure 1463, basing risk adjustment on the 2728 form could potentially lead to cherry-picking of healthier patients or patients with primary care physicians over patients without one, or patients with other less desirable characteristics.

Moreover, the proposed measure does not address, and may even penalize dialysis providers who include robust advanced care planning, palliative care, and/or hospice services to improve end-of-life care for patients.

A measure like 0369 would be helpful if it used data from sources other than CMS Form 2728 that is more precise for risk adjustment.

Measure 0258: The Consumer Assessment of Healthcare Providers and Systems (CAHPS) In-Center Hemodialysis Survey. The proportion of patients answering each of response options for each of the items summed across the items within a composite to yield the composite measure score.

ASN concurs with MAP's support for Measure 0258. The CAHPS measures many useful components of a patient's experience in the in-center dialysis unit. ASN is not certain that the description of the numerator and denominator was clearly delineated in the MAP document, but the society supports the CAHPS survey.

Measure 1460: Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.

ASN agrees with MAP's recommendation to support Measure 1460, provided that it is limited to patients with central venous catheters and includes patients in home hemodialysis programs. Moreover, the society is concerned that the measure not unfairly penalize small units. ASN also recommends excluding samples that may turn out to be "contaminants" such as organisms commonly associated with skin flora that are not true bacteremia.

Measure 2769: Risk adjusted facility level transfusion rate "STrR" for dialysis patients.

ASN agrees with MAP's recommendation not to support this measure, and concurs that the concept would require considerable modification or further development. In particular, ASN is concerned that gaps in information and testing exist. For instance, there are difficulties involved with tracking and reporting transfusions given in an in-patient hospital versus an emergency room outpatient setting. Moreover, there is no way of telling how many transfusions were administered the way they are currently coded. Transfusions are coded to indicate if they were given on any single day, not the number of transfusions given. Thus, by this metric, a patient who receives two transfusions in one day provides half the transfusion events compared with a similar patient who receives two transfusions on two separate days. ASN is also concerned that the "expected" threshold for transfusion may vary from place-to-place or provider-to-provider and is often influenced by acute medical or surgical issues unrelated to the quality of care delivered in dialysis facilities.

Measure 2774: Percentage of eligible patients for whom the facility has evaluated risks, benefits, and alternative treatment options for anemia and the patient participated in a decision regarding anemia treatment strategy.

ASN concurs with MAP not to recommend use of Measure 2774 at this time. While involving patients in their care is critical to best clinical outcomes, it is not clear how Measure 2774 would work in practice. There are no defined, standardized expectations for explaining risks and benefits of transfusions and treatment options, so it is not clear that a measure like this would result in meaningful patient outcomes.

Measure 0226: Percentage of end-stage renal disease patients aged 6 months and older receiving hemodialysis or peritoneal dialysis during the time from October 1 (or when the influenza vaccine became available) to March 31 who either received, were offered and declined, or were determined to have a medical contraindication to the influenza vaccination.

ASN agrees with MAP's support for the concept of Measure 0226. Influenza illness contributes to more than 36,000 deaths annually, indicating that it has a significant public health impact.

However, few randomized controlled trials have been performed in high-risk populations, and it is widely known that the efficacy of the influenza vaccine is blunted in dialysis patients due to an attenuated humoral immunity response. Despite the lack of significant high-quality evidence as to the utility of a dedicated influenza vaccination program in decreasing the risk for hospitalizations and morbidity/mortality from influenza, this initiative seems reasonable when considering that it is generally safe, seems to be a low-risk intervention, and may be cost-effective.

If implemented, tracking patients who received the vaccine at another facility (i.e., a hospital or primary care clinic) would have to be addressed in a manner that does not unduly burden dialysis providers to accurately record when and where this vaccine was given. One of the most important factors in preventing outbreaks of influenza is the vaccination of all dialysis facility occupants—physicians, nurses, dialysis techs, social workers, etc. ASN recommends including dialysis facility staff as well as patients in this measure.

Measure 1653: Inpatients 65 years and older and 6-64 years of age who have a high-risk condition who are screened for 23-valent Pneumococcal Polysaccharide Vaccine (PPV23) status and vaccinated prior to discharge if indicated.

ASN agrees with MAP's recommendation not to support this measure at this time. Neither the dialysis facility nor the outpatient treating nephrologist typically have control over vaccination or other care provided during a hospitalization.

Measure 0251: Percentage of end-stage renal disease patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who: (1) have a functional autologous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); (2) have a functional AV graft (computed and reported separately); or (3) have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately).

MAP supports this measure, and ASN supports the concept of this measure but suggests a few modifications that should to be addressed prior to implementation. ASN recommends that patients with limited lifespan, who are on hospice care, or are expected to receive an imminent transplant should be excluded. ASN also recommends that the requirement for *annual* evaluation by a vascular surgeon or interventional nephrologist be eliminated as this creates an undue burden on patients and physicians, increases unnecessary costs of care, and would not necessarily lead to improved outcomes.

Additionally, nephrologists should be able to certify that certain patients are not appropriate candidates for a fistula (such as patients near the end of life who are not in hospice) and those patients should be exempted from the measure. ASN also believes that the requirement should only be for referral for AV access evaluation; whether a referred patient is actually seen for evaluation is largely under the control of the patient, not the dialysis facility. Lastly, ASN recommends tracking the total number of patients who are deemed 'catheter dependent' to monitor for unusually high (e.g. 30 percent) 'catheter dependent' rates.

<u>Pediatric Measures</u>

ASN believes the Quality Improvement Program structure is not adequate at this time to include pediatric metrics due to the low number of patients insured by Medicare in most pediatric facilities. However, the society supports efforts to develop pediatric-specific measures, in addition to measures that apply to both pediatric and adult ESRD patients, in an effort to provide improved care and create greater transparency for pediatric patients and their families.

Measure 1418: Percentage of all pediatric (less than 18 years old) 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 believes it is reasonable to ask that pediatric patients have dialysis dose assessed and consequently agrees with MAP's support for the concept of this measure. However, the society recommends adding that, as for adult patients, pediatric patients should have a minimum dose of dialysis as determined by achieving a spKt/V of >1.2.

Measure 1424: Percentage of all pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin.

ASN concurs with MAP's support for this measure if evidence suggests there is a performance gap that necessitates it.

Measure 1425: Percentage of pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.

ASN concurs with MAP's support for the concept of this measure but recommends adding a target nPCR. Information on pediatric hemodialysis patient nutritional status supports the use of nPCR to monitor nutritional status in these patients. Assessment of nutrition status is an essential component of hemodialysis adequacy measurement. nPCR should be measured monthly by using either formal urea kinetic modeling or algebraic approximation.

Measure 1433: 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 simultaneous values of serum ferritin concentration were less than 100 ng/mL and transferrin saturation (TSAT) was less than 20 percent who received IV iron or were prescribed oral iron within the following 3 months.

ASN agrees with MAP's support for the concept of this measure provided that it is limited to pediatric patients receiving ESA therapy. As written, the measure suggests that a hemoglobin count less than 11.0 g/dL in the presence of low TSAT and serum ferritin concentration must be treated. Insufficient evidence exists to support such a recommendation. However, the evidence for treating patients with low iron parameters is stronger for patients also treated with ESAs.

Additional Comments

ASN appreciates the opportunity to comment on the NQF MAP Pre-Rulemaking Input Report. Unfortunately, the NQF comment submission website limits public commenters to providing no more than 3,000 characters in each of the nine comment sections for the 209-page draft report. The draft report reviews 478 potential quality measures that, if implemented by CMS or other payers, will have a powerful influence on the care patients receive. This comment letter on just 21 of those measures is nine pages long and exceeds 20,000 characters.

Patients deserve thoughtful, nuanced consideration of the scientific evidence supporting potential quality measures—and of the measures' potential intended and unintended consequences. Developing high-quality performance measures is an extremely difficult process that demands meticulous deliberation of the possible risks and benefits. In future years, ASN recommends that NQF eliminate restrictions on the number of characters public commenters may use on the comment submission website so stakeholders may provide more detailed, meaningful feedback.

Again, thank you for your time and consideration. ASN stands ready to discuss any of these suggestions with NQF if it would be helpful. To discuss ASN's comments, please contact ASN Manager of Policy and Government Affairs Rachel N. Shaffer at rshaffer@asn-online.org or (202) 640-4659.

Sincerely,

Bruce A. Molitoris, MD, FASN
President