ASN LEADING THE FIGHT AGAINST KIDNEY DISEASE

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Christine K. Cassel, MD
President and Chief Executive Officer
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15th Street, NW
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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) Pre-Rulemaking Input Report. ASN is the world's leading organization of kidney health professionals, representing nearly 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 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 patient care, and is committed to actively participating in the consideration and selection of evidence-based quality measures related to kidney disease care and kindly submits the following comments on the proposed end-stage renal disease-related measures for your consideration.

Measure XDGAM: Pediatric Peritoneal Dialysis Adequacy: Frequency of Measurement of Kt/V.

Measure XCBMM Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V.

ASN conditionally supports measures XCBMM and XDGAM overall at this time, noting that these measures correspond directly to existing KDOQI guidelines. However, ASN

observes that these measures should be updated in the future to reflect any subsequent KDOQI updates.

Measure XDGBA: ESRD Vaccination – Lifetime Pneumococcal Vaccination.

Measure XDEFL: ESRD Vaccination - Pneumococcal Vaccination (PPSV23).

Measure XDEFH: Pneumococcal Vaccination Measure (PCV13).

Measures XDGBA, XDEFL, and XDEFH all pertain to dialysis patient pneumococcal vaccination status. Measure XDGBA refers to the percentage of patients age 2 years old and older who have ever received either the PPSV23 or the PCV13, were offered and declined the vaccination or were determined to have a medical contraindication. XDEFL specifically covers the PPSV23 vaccine while XDEFH specifically covers the PCV13 vaccine. Traditionally, the PCV13 is used in children, although, for 'chronic renal failure', the Advisory Committee on Immunization Practices (ACIP) recommends both the PPSV23 and the PCV13. This recommendation is based on the definition of chronic renal failure as an immunocompromised state. However, limited outcome data exists assessing the effectiveness of this strategy. Of note, per the ACIP, individuals who have an indication to receive both PCV13 and PPSV23, such as dialysis patients, should be vaccinated according to the following schedule:

- For patients who have not previously received either PCV13 or PPSV23, a single dose of PCV13 should be given, followed by a dose of PPSV23 at least eight weeks later.
- For patients who have previously received one or more doses of PPSV23, a single dose of PCV13 should be given one or more years after the last PPSV23 dose was received.
- For patients who require additional doses of PPSV23, the first such dose should be given no sooner than eight weeks after PCV13 and at least five years after the most recent dose of PPSV23.
- Patients <65 years of age who have functional or anatomic asplenia or who are immunocompromised should be revaccinated one time five years after the initial dose, and again at or after age 65 (and at least five years after the previous dose).

ASN agrees that encouraging immunization where indicated is a worthy goal. However, as the society observes that none of the three overlapping measures have been refined and none of them have been tested. ASN would support eventual adoption of XGDBA (the simplest of the three proposals) once reporting has been streamlined and the measure appropriately refined.

As currently written, XDEFL fails to account for potential medical complexities associated with pneumonia vaccination, including issues with recent transplantation as well as the interval duration between PCV13 and PPSV23 administration. The society's trepidation to support measure XDEFL and XDEFH reflects the fact that they are highly specific in a field that is subject to rapid change. For example, when newer vaccines

are developed, how will they be integrated into these measures and when will this occur? These logistic issues are similar to those discussed below in regards to influenza vaccination.

In sum, ASN supports the XDGBA measure in concept although notes that testing is required for measure validity, and ASN does not support XDEFL and XDEFH.

Measure XDGAF: Hepatitis B vaccine coverage in hemodialysis patients.

ASN does not support measure XDGAF in its current form, and feels this measure needs to be fully specified. As currently written, the measure leaves many important questions unanswered. For example, what if one cannot prove that a patient has received three vaccine doses but has adequate Hepatitis B Ab titers? How should a facility respond to a patient with both Hepatitis B core Ab + and Hepatitis B S Ab + due to known prior infection? What is the denominator? ASN also notes that, in the United States, Hepatitis B vaccination is now routinely administered during childhood. As such, the society expects that there will be a substantial number of dialysis patients moving forward who do not have well documented records of vaccination available to the dialysis facilities. If this measure were to be implemented, how would a facility respond to such ambiguity, as there is no statement regarding serology results in this measure? Finally and most importantly, Hepatitis B testing and vaccination is described in detail in the Conditions for Coverage (Tag V126). ASN does not support implementation of measure XDGAF at this time because of a lack of details, redundancy with existing regulations, and, in the absence of details, potential conflicts with these existing regulations.

Measure XDEGC: Measurement of Plasma PTH Concentration.

ASN does not support Measure XDEGC. PTH is typically measured quarterly in most dialysis facilities, and at present there is no evidence supporting a performance gap in this aspect of care. Moreover, no clinical practice guidelines rated above level 2D currently exist delineating: 1) how to measure PTH; 2) how to respond to PTH results; or 3) the optimal frequency of PTH measurement. Moreover, the proposed measure has not been tested, and the additional data reporting requirement—including data entry with the specific assay described— may be substantial.

Measure XDEFF: Standardized Kt/V.

ASN does not support Measure XDEFF. Given the increasing complexity of hemodialysis regimens, there may be a role for future use of stdKt/V when examining small molecule clearance across hemodialysis strategies. However, at present, ASN observes that optimal small molecule clearance remains uncertain, even for thrice weekly hemodialysis, and even less certain for more frequent hemodialysis modalities. The society believes that more data may be helpful to be able to better study these treatment strategies. ASN notes that most LDOs do already collect these data, but at the same time recognizes that there could be potential data collection feasibility and

cost of data entry concerns. ASN also maintains concerns that there are no data to support specific targets. Accordingly, ASN believes extensive piloting and refining of this measure would be necessary before it can be considered for adoption.

In sum, ASN would support a future measure on this topic but does not support the current measure due to insufficient validity testing as well as potential feasibility of data collection and cost of data entry.

Measure XDEFE: Surface Area Normalized Kt/V.

ASN does not support Measure XDEFE. While ASN realizes that there is ongoing debate about how to best account for volume and acknowledges that opinion leaders in this field posit that surface area normalization may explain the discrepant results in the HEMO study by sex, this concept remains a research question. Additionally, there is a tremendous data gathering effort required for this measure as well as a lack of specificity about how to, and how often to, determine height (which is in actuality a complicated issue in clinical practice and research studies). There is no guideline supporting this measure and there is no information as to what to do with these data.

Accordingly, ASN does not support measure XDEFE.

Measure XDEGB: Percentage of Dialysis Patients with Dietary Counseling.

ASN does not support measure XDEGB. While ASN concurs with the measure sponsor that dietary counseling is important, the society maintains numerous issues with this measure as proposed. 1) Dietary counseling is already extensively discussed within the Conditions for Coverage, with notes from dieticians required more frequently than stated in this proposed metric for each dialysis patient; 2) Not all patients require counseling on dietary phosphorus, and the emphasis on phosphorus over fluid in this proposed measure is vexing; 3) The reliability and validity of this measure remains very uncertain; and 4) Aside from the proposed measure's specificity regarding dietary phosphorus, much else remains vague, such as what is dietary counseling, and who might be acceptable to provide this counseling.

Accordingly, ASN does not support measure XDEGB.

Measure XDEGA: ESRD Vaccination - Timely Influenza Vaccination.

Measure XDEFM: Full-Season Influenza Vaccination (ESRD Patients).

ASN is concerned that measures XDEGA and XDEFM would create an unnecessary burden for ESRD facilities, and notes that the measures as currently written remain vague and insufficiently detailed. It is unclear as to the documentation required to demonstrate immunization that occurs outside the dialysis facility to satisfy this metric. The issue of immunization in children remains complex and may present an additional burden for dialysis facilities. Lastly is the topic of record keeping. The data elements

necessary for testing are “not currently required and/or available” in the CROWNWeb data repository, and CMS currently reports that this measure has not been tested for reliability or validity.

In sum, ASN does not support the measure as currently proposed but does supports a measure on influenza vaccination in concept, focusing on a single measure rather than two competing measures, preferably similar to XDEFM (seasonal) once this is better refined. Specifically, the dates for vaccination should align between the numerator and the denominator, patients initiating dialysis late in an influenza season should not be required to be vaccinated, and there needs to be a comment regarding influenza vaccine availability, as there have been shortages in recent years.

Measure E0260 /NQF 0260: Assessment of Health- Related Quality of Life (Physical & Mental Functioning).

While ASN acknowledges the importance of patient-specific quality of life assessments, ASN does not support the measure as currently proposed, reflecting the following concerns: 1) redundancy with the Conditions for Coverage; 2) survey burden when viewed in concurrent context with dialysis facility specific surveys as well as current twice yearly ICH-CAHPS requirements; and 3) unclear wording of the measure description, which presumably refers to the use of the KDQOL instrument; and, 4) facility burden for both assisted administration as well as documentation of results and the documentation of the multiple exclusions from administration.

Measure XAHMH: Percent of patients with a UFR greater than 10 ml/kg/hr.

ASN does not support Measure XAHMH. The proposed measure is discrepant between the title and the numerator, with one specifying a UF rate of 10 and the other of 13 ml/kg/hour. There are many issues with this measure that make it very inappropriate to be advanced at the current time. First, there is no consensus or data regarding an optimal ultrafiltration rate. In fact, both levels mentioned in the measure (10 ml/kg/hour and 13 ml/kg/hour) reflect semi-arbitrary thresholds analyzed in a recent administrative database of dialysis patients. Second, while many providers do feel that slowing down the ultrafiltration rate is important, there is no consensus to this effect. Third, there are only two ways to reduce ultrafiltration rate – increase dialysis time or decrease total ultrafiltration. While ASN and most providers are generally supportive of increasing dialysis time, there are no clinical trials of improved mortality outcomes and there are patient symptoms that occur with prolonged dialysis, even with smaller dialysis membranes and reduced blood flow rates. In fact, this is the goal of the first major ongoing US pragmatic dialysis trial, the TIME Trial. Fourth, the ultrafiltration rate may differ among sessions and notably, typically differs by day of the week. Accounting for this factor would be important. ASN applauds MAP for recognizing that volume control is extremely important, but we feel that the specificity of the proposed measure, whether using a threshold of 10 or 13 ml/kg/hour, is unsupported by data at the current time. The society notes that a recently convened TEP failed to support a measure on this

topic and that a KDOQI guideline panel on hemodialysis adequacy, which has already convened, is expected to address this specific question.

In sum, ASN opposes this measure given the paucity of evidence to support this measure and potential issues with measure validity.

Measure E0029 / NQF 0029: Counseling on Physical Activity in Older Adults: 1. Discussing Physical Activity 2. Advising Physical Activity.

While exercise and physical activity are important for dialysis patients, this measure is poorly defined. As worded, it seems to require an additional patient survey, and is beyond the scope of dialysis facilities.

Measure E0393/ NQF 0393: Hepatitis C: Testing for Chronic Hepatitis C – Confirmation of Hepatitis C Viremia.

ASN does not support Measure E0393. Hepatitis C testing is currently widely performed by facilities, however, the role for referral for treatment and whether safe interventions to treat hepatitis C in dialysis patients exist remain uncertain. While Hepatitis B testing is extremely important, there is little role for Hep C RNA testing in the dialysis facility, and, for issues related to Hepatitis C, dialysis facilities are already governed by the CfCs. Given these factors, most notably the uncertain role for referral of these patients to a specialist given competing comorbid conditions and the lack of well-accepted, easily tolerated and efficacious therapies at the current time for dialysis patients with Hepatitis C, this proposed measure is premature and likely unnecessary.

Measure E0004 / NQF 0004: Initiation and Engagement of Alcohol and Other Drug Dependence Treatment.

While an important measure for the health of individuals and a topic that the nephrology team should be aware of and potentially be engaged in, ASN does not believe that the quality of care delivered either by dialysis facilities or nephrologists or nephrology practices should be judged using this measure as this is beyond the purview of the dialysis facility. While there are social work interventions available within a dialysis facility, these issues are beyond the scope of dialysis care.

ASN therefore recommends against approving this proposed measure.

Measure E0431/ NQF 0431: Percentage of healthcare personnel (HCP) who receive the influenza vaccination.

ASN applauds the overall purpose of this quality measure but suggests that it needs to be validated to assess the feasibility of reliable immunization data collection. This measure could potentially represent a significant additional reporting burden on dialysis facilities without generating reliable data. Members of the healthcare team, including to

medical students, residents, and other personnel who received immunizations, may not possess the documentation at the time of their visit to the dialysis facility. The logistics of reliably obtaining this information need to be assessed prior to implementation. Finally, a measure on this topic would needs to be synchronized with a similar measure proposed by University of Michigan Kidney and Epidemiology Cost Center (UM-KECC).

ASN opposes this measure at the current time, primarily because the logistics of implementation of this measure could be very complicated and the reporting burden quite high.

Measure E0420 NQF 0420: Pain Assessment and Follow-Up.

ASN agrees that chronic pain is an important issue for dialysis patients. The society notes that the burden of this measure, as worded, is very high for an outpatient dialysis facility. Recognizing the dialysis patients typically dialyze at a center three times per week, the requirement for documentation of a pain management plan at each encounter is excessive, particularly for chronic pain. Moreover, the CfCs already elaborate on care plan items such as pain in considerable detail. This proposed measure has not been adequately studied or validated in dialysis, and the tools to assess pain in this population remain insufficient.

Measure E0418/ NQF 0418: Screening for Clinical Depression.
Rates of depression among dialysis patients are presumably very high, although instruments remain poorly validated for assessing depression versus instruments identifying competing somatic symptoms that are associated with dialysis itself. The efficacy of therapies for treatment of depression in dialysis patients is also poorly studied, with only a few small trials addressing this important issue.

Accordingly, ASN supports screening for depression with a standardized tool that could be chosen by the individual facility. However, at the current time ASN cannot support this metric as it does not apply to dialysis facilities. The society would be pleased to consider supporting a future measure designed to address depression screening in dialysis facilities.

Additional Comments

ASN supports parsimony in measures. ASN believes that it is necessary and beneficial to have metrics based on important indicators of care quality in ESRD. 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, and minimizing patient survey burden is important for validity and achieving desired outcomes of measures. It is within these contrasts that we comment 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,

Thomas H. Hostetter, MD
Public Policy Board Chair