KIDNEY CARE PARTNERS

July 11, 2015

National Quality Forum
1030 Fifteenth Street, NW
Suite 800
Washington, DC 20005

RE: NQF Renal Project

Kidney Care Partners (KCP) appreciates the opportunity to comment on the National Quality Forum's (NQF) Renal Draft Report. KCP is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, health care professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with both chronic kidney disease and end stage renal disease. We greatly appreciate NQF undertaking this important work.

As an operating premise, KCP's support assumes, unless otherwise indicated, use of facility-level measures in the Quality Incentive Program (QIP) and clinician-level measures in the Physician Quality Reporting System, which is currently for public reporting but is transitioning to payment/value-based purchasing.

Overarching Comment on CMS Hemodialysis and Peritoneal Dialysis Adequacy Measures

KCP believes that CMS stipulated at the in-person meeting of the NQF Standing Committee that the upper limits on all CMS adequacy measures would be removed from the specifications and that NQF indicated that the Standing Committee should account for this in its deliberations and voting on them. We note, however, the draft report's language does not consistently indicate this to be the case for each measure and believe this should be corrected.

Measures Recommended for Endorsement by NQF Renal Standing Committee

1. **NQF 0251 Vascular Access: Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement (KCQA):** Percentage of ESRD patients aged 18 years and older receiving HD during the 12-month reporting period and on dialysis >90 days who: 1) have a functional AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); or 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).

   Comment: **Support.** KCP continues to supports this clinician-level measure.

2. **NQF 0256 Minimizing Use of Catheters and Chronic Dialysis Access (CMS):** Percentage of patient-months on maintenance hemodialysis during the last hemodialysis treatment of the month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.

   Comment: **Support, with qualifications.** KCP recognizes the importance of minimizing catheters, although as we note in our comments on NQF 0257 (below), catheters are clinically important in some populations. We continue to be concerned, however, about the lack of an AV graft measure in the CMS portfolio.

3. **NQF 0257 Maximizing Placement of AVF (CMS):** Percentage of patient-months for patients on maintenance hemodialysis during the last hemodialysis treatment of month using an autogenous AVF with two needles.

   Comment: **Support, with qualifications.** KCP recognizes the importance of AVFs, but continues to be concerned about the lack of an AV graft measure in the CMS portfolio. We also believe the measure should exclude hospice patients and patients with an expected lifespan of <6 months; catheters would be clinically appropriate in these populations. Additionally, we are aware that catheters are becoming an access-to-care issue, whereby it may be difficult for some patients with catheters (appropriately) to receive treatment at some facilities owing to the desire to minimize use of catheters or be penalized by the measure as currently being implemented; excluding patients who appropriately have a catheter would address this issue.

4. **NQF 0318 Delivered Dose of Peritoneal Dialysis Above Minimum (CMS):** Percentage of all patient-months for patients ≥18 years old whose delivered peritoneal dialysis dose was a weekly Kt/V_{urea} of between spKt/V >=1.7 and spKt/V <=8.5 (dialytic + residual).

   Comment: **Support.** KCP continues to support this measure. We also again note that while the submission forms to NQF note the frequency should be at least every four months, the specifications no longer do so; we believe this should be clarified. KCP supports the Committee's recommendation to remove the upper limit from the specifications.

5. **NQF 0321 Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute (RPA):** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V ≥1.7 per week measured once every four months.

   Comment: **Support.** KCP continues to support this clinician-level measure. KCP supports the Committee's recommendation to remove the upper limit from the specifications.

6. **NQF 1424 Monthly Hemoglobin Measurement for Pediatric Patients (CMS):** Percentage of patient-months of all pediatric (<18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin during the reporting period.

   Comment: **Support.** KCP continues to support this measure.

7. **NQF 1425 Measurement of nPCR for Pediatric Hemodialysis Patients (CMS):** Percentage of patient-months of pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.

   Comment: **Support.** KCP continues to support this measure.

8. **NQF 1667 Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level <10 g/dL (RPA):** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a hemoglobin level <10 g/dL.

   Comment: **Support.** KCP continues to support this clinician-level measure.

9. **NQF 1662 Angiotensin Converting Enzyme (ACE) Inhibitor of ACE Receptor Blocker (ARB) Therapy (RPA):** Percentage of patients aged 18 years and older with a diagnosis of CKD (not receiving RRT) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period.

   Comment: **Support.** KCP supports this clinician-level measure.

10. **NQF 2594 Optimal ESRD Starts (Permanente Federation):** The percentage of new ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, initiating home dialysis, or initiating outpatient in-center hemodialysis via arteriovenous fistula (AVF) or AV graft.

    Comment: **Generally support with noted qualifications, but oppose for implementation in dialysis facilities.** KCP acknowledges that this team/population/integrated-system/health plan level measure is an important and conceptually appropriate measure, but believes it is only feasible in fully integrated delivery care systems or large physician groups. As constructed, the measure cannot be applied to dialysis facilities, or even ESCOs, because neither includes CKD patients. While the "clinician/team" level specified in the measure (i.e., the nephrology practice) could be applied, sufficient patient volumes will be an issue. Specifically, the number of patients starting ESRD care within a practice within the defined 12-month period of time might not be sufficient to provide statistically valid data. Likewise, the measure doesn't account for the fact that approximately 40% of patients have not yet been seen by the nephrologist they will be assigned to at the time of dialysis initiation.

    Additionally, we recommend that the developer consider three exclusions addressing scenarios in which a permanent access may not be appropriate. These three groups represent a small number of patients cumulatively, but they should nevertheless be appropriately excluded:

    - Patients with a limited life expectancy, where not placing a permanent access may be more consistent with the patient's goals;
    - Patients who are uncertain whether they wish to pursue long-term treatment and desire a time-limited trial of dialysis; and
    - Patients with acute kidney injury without prior CKD who ultimately don't recover renal function; these patients will likely use a catheter for their first

treatment, and it is appropriate to wait up to four months to see if they will recover function before pursuing permanent access.

Finally, we have identified three potential unintended consequences that should be closely monitored:

- There could be some "misuse" or misrepresentation of an "optimal start". For instance, patients who have not received appropriate pre-ESRD care might be persuaded to acutely start peritoneal dialysis in the hospital, and then be kept on this course so as to improve the measured entity's performance.
- The measure excludes patients with a single needle in the AVF that have blood return via their catheter. This could incentivize premature insertion of both needles for the first treatment, leading to damage of immature AVFs. Catheters could then be used in subsequent treatments, without impacting measure performance.
- The measure will likely penalize providers caring for a disproportionate percentage of patients with low socioeconomic status, since these individuals most often have not seen a nephrologist prior to beginning treatment; safety net providers may be inappropriately penalized.

11. **NQF 2701 Avoidance of Utilization of High Ultrafiltration Rate (≥13 ml/kg/hour, KCQA):** Percentage of adult in-center hemodialysis patients* in the facility whose average UFR ≥13 ml/kg/hour. *To address the fact that patients may contribute varying amounts of time to the annual denominator population, results will be reported using a "patient-month" construction. The calculation period is defined as the same week that the monthly Kt/V is drawn.

    Comment: **Support.** KCP believes fluid management is a critical area to address through performance measurement and supports this measure.

12. **NQF 2704 Minimum Delivered Peritoneal Dialysis Dose (CMS):** Composite of the adult (NQF 0318) and pediatric (NQF 2706) measures.

    Comment: **Support.** KCP supports this measure. We recommend the frequency be clarified in the individual measures, so do so for the composite as well. KCP supports the Committee's recommendation to remove the upper limit from the specifications.

13. **NQF 2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (CMS):** Percent of pediatric peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/V_{urea} of between spKt/V =1.8 and spKt/V <8.5 (dialytic + residual).

    Comment: **Support.** KCP continues to support this measure with the removal of the upper limit. We also recommend the frequency be clarified.

Measures Recommended for Reserve Status by NQF Renal Standing Committee

14. **NQF 0249 Delivered Dose of Hemodialysis Above Minimum (CMS):** Percentage of all patient-months for adult patients (≥18 years old) whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was an spKt/V ≥1.2 and spKt/V ≤5.0.

Comment: **Support Reserve Status.** KCP supports the Committee's recommendation of Reserve Status for this measure, with the upper limit removed.

15. **NQF 0255 Measurement of Serum Phosphorus Concentration (CMS):** Percentage of all adult (>18 years of age) peritoneal dialysis and hemodialysis patient-months included in the sample for analysis with serum or plasma phosphorus measured at least once within the month.

    Comment: **Support Reserve Status.** KCP supports the Committee's recommendation of Reserve Status for this measure. We applaud CMS for revising the specifications to include plasma as an acceptable substrate and note that the title of the measure should reflect this as well.

16. **NQF 0323 Adult Kidney Disease: Hemodialysis Adequacy: Solute (RPA):** Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week for ≥90 days have a spKt/V ≥1.2.

    Comment: **Support Reserve Status.** KCP supports the Committee's recommendation of Reserve Status for this clinician-level measure.

Consensus Not Reached by NQF Renal Standing Committee

17. **NQF 1423 Minimum spKt/V for Pediatric Hemodialysis Patients (CMS):** Percentage of patient-months for all pediatric (<18 years old) in-center hemodialysis patients who have been on hemodialysis for >90 and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis using the UKM or Daugirdas II formula was between spKt/V =1.2 and spKt/V <5.0.

    Comment: **Support.** KCP continues to support this measure with the upper limits removed.

18. **NQF 2702 Post-Dialysis Weight Above or Below Target Weight (KCQA):** Percentage of patients* with an average post-dialysis weight ≥1 kg above or below the prescribed target weight. *To address the fact that patients may contribute varying amounts of time to the annual denominator population, results will be reported using a "patient-month" construction. The calculation period is defined as the same week that the monthly Kt/V is drawn.

    Comment: **Support.** KCP believes fluid management is a critical area to address through performance measurement and supports this measure.

    KCP notes that on page 19, line 626 in the discussion about the measure, the word "little" is a typographical error that should be removed from the text. We confirmed with NQF staff that this was a typo and comment here to ensure its correction in the voting draft.

Measures Not Recommended by NQF Renal Standing Committee

19. **NQF 1454 Proportion of Patients with Hypercalcemia (CMS):** Percentage of adult dialysis patients with a 3-month rolling average of total uncorrected serum or plasma calcium >10.2 mg/dL.

    Comment: **Oppose.** While KCP applauds CMS for the revision of the specifications to include plasma as an acceptable substrate, KCP continues to oppose this measure. We reiterate that in the absence of metrics for other related mineral disturbances

(e.g., phosphorous, PTH), NQF 1454 will not meaningfully impact outcomes or encourage proper bone mineral metabolism management. Moreover, we note that only a very small number of dialysis patients are afflicted with hypercalcemia and that there is not a sufficient gap in this aspect of care to warrant continued endorsement of this measure or its use in the QIP.

20. **NQF 1460 Bloodstream Infection in Hemodialysis Outpatients (CDC):** Adjusted Ranking Metric (ARM) and Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.

    Comment: **Support unadjusted measure; not prepared to support ARM and SIR.** KCP strongly believes infections are an important quality and safety issue, and KCP did support and continues to support NQF 1460 in its ***unadjusted*** format for purposes of NQF endorsement only. However, KCP is <u>not</u> prepared to support NQF 1460 with the ARM or SIR until there is more clarity in the methodology.

    KCP appreciates the additional information provided in the NQF measure submission documents on how the measure will be calculated. However, despite repeated inquiries to the CDC, KCP has been unable to get additional specifics on the ARM methodology, and much information is still missing. Our concerns include, but are not limited to, issues such as the following:

    - The language in the documents is frequently vague, imprecise, and at times even contradictory. For instance, reference is made to the ARM's reliance on a Bayesian random effects hierarchical adjustment model, but verbiage in the submission documents report that "the only risk adjustment performed is stratification of rates by vascular access type."
    - The developer reports that said stratification also accounts for "many other (both measured and unmeasured) factors that are correlated with vascular access type." These reportedly include variables such as age, the presence of certain comorbid conditions, and illness severity, but neither the actual list of variables nor the rationale for inclusion of those particular variables are provided for review.
    - URLs listed in the submission documents and online searches for more information yield only the one-page high-level summary of the methodology that was available last year. This document also indicates that a Bayesian random effects hierarchical model is required.
    - Finally, we note that the "expected" value in the SIR calculation requires a comparison to BSI rates in the specific vascular access strata from a "standard population," but no information on what this standard population is or how it is defined is provided in the documents or can be identified online.

    We also have data concerns about the measure's implementation in the QIP that we have conveyed to CMS.

21. **NQF 1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <9 g/dL (RPA):** Percent calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD who are receiving hemodialysis or peritoneal dialysis have a hemoglobin level <9 g/dL.

C*omment:* **Oppose.** KCP supported a previous version of this clinician-level measure, wherein the hemoglobin threshold was defined as <10, rather than <9 g/dL. While the <9 measure would establish a lower hemoglobin threshold to complement NQF 1666—*ESRD Patients with Hemoglobin Level >12.0 g/dL*, KCP has concern that <9 g/dL is too low a value**.** Contemporary evidence indicates that the longer a patient has a hemoglobin value less than 10, the higher the risk of transfusion. We also note that the corresponding NQF-endorsed pediatric anemia measure (NQF 1667) uses a lower hemoglobin parameter of <10, and that the <9 measure is thus not harmonized in that regard.

22. **NQF 2699 Anemia of Chronic Kidney Disease: Dialysis Facility Standardized Transfusion Ratio (STrR, CMS):** Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at the facility to the number of eligible transfusions that would be expected under a national norm, after accounting from a predictive model that accounts for patient characteristics within each facility.

    Comment: **Oppose.** KCP has consistently opposed this measure because it does not adjust for hospital- or physician-related factors. We reiterate that the literature documents that both hospital and physician factors impact transfusion rates in other areas and that there is no reason to think transfusions related to ESRD patients are any different. We again urge CMS to review its data and document why the risk model should not account for these variables—i.e., the burden is on the developer to conduct the analyses and show that accounting for hospital-level and physician-level factors is not important in this area. Such details are particularly important because facilities do not have access to transfusion data; the developer must therefore provide transparency in this regard. We also are concerned with the approach and assumptions for the predictive model, which posits to reveal an actual versus predicted rate, when the basis for the ratio comes from claims data and not EMR data. The documentation fails to demonstrate it accurately predicts and identifies those who have had transfusions, and additional analytic rigor must be brought to bear for this measure.

23. **NQF 2700 Ultrafiltration Rate >13 ml/kg/hour (CMS):** Percentage of patient-months for patients with an ultrafiltration rate >13 ml/kg/hour.

    Comment: **Oppose.** KCP believes fluid management is a critical area to address through performance measurement, but opposes NQF 2700 and supports NQF 2701. NQF 2700 relies on a single data point per month, whereas NQF 2701 relies on an average across the treatments in the week the Kt/V is performed. Relying on a single data point will disadvantage those facilities on a Monday/Tuesday draw, since patients typically have greater fluid at the first treatment of the week; a single data point also is easier to game. The CMS measure also lacks a time component. In contrast, the KCQA measure, NQF 2701, includes patients in the numerator only if they have an average dialysis time of <240 minutes for the calculation period. The inclusion of the time component is critical to avoid an unintended adverse consequence that could result from the cascading effect of extending an individual's treatment time, given the upper rate of fluid removal is limited by the measure. Specifically, if an individual goes beyond his/her stated treatment time such that the following patient must start later, the second patient is likely to expect and want treatment to end at the "usual" time and thus be under-treated. The very real

potential for harm to this "third-party" individual due to measurement-related actions for other patients is the basis for the KCQA inclusion of the time component.

Again, thank you for undertaking this important project; we appreciate the opportunity to provide KCP's consensus comments. Please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.530.9524) if you have any questions.

Sincerely,

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American Nephrology Nurses Association
American Renal
American Society of Pediatric Nephrology
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