January 9, 2012

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

Subject: National Voluntary Consensus Standards for Renal Disease, NQF Member Comments

I. General Comments
Thank you for the opportunity to comment on the National Quality Forum’s (NQF) draft document, National Voluntary Consensus Standards for Renal Disease. Kidney Care Partners (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 (ESRD). We greatly appreciate NQF undertaking this important work.

The NQF report recommends that 13 measures (four new and nine previously endorsed) addressing the topics of mortality, anemia, cardiovascular care, dialysis adequacy, mineral metabolism, and vascular access be endorsed as national voluntary consensus standards. Our understanding is that NQF endorsement historically has been for the purposes of public reporting and internal quality improvement. As an operating premise, however, KCP has assumed that endorsement means the Centers for Medicare and Medicaid Services (CMS) may use a measure in the Quality Incentive Program (QIP)—i.e., for payment/value-based purchasing. And while CMS states it will use rulemaking to implement measures for the QIP, for purposes of clarity we have stated KCP’s support for each measure in the context of intended use. Additionally, when considering previously endorsed measures, KCP assessed whether it should continue its previous support or opposition based on whether there have been changes in the science/evidentiary base since 2008 and whether performance on the measure has “topped out”, leaving little or no room for improvement.

Again, thank you for undertaking this important project; we appreciate the opportunity to provide KCP’s consensus comments. Please do not hesitate to contact us if you have any questions.

II. Measures Recommended by NQF
KCP’s comments on the 13 measures recommended by NQF are as follows:

a. NQF 0369 Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (CMS): Risk-adjusted standardized mortality ratio (observed/expected deaths) for dialysis facility patients during a four-year time period.

Comment: KCP had previously supported this measure, believes greater transparency in the methodology must be provided.
b. **NQF 1666 Patients on ESA with Hemoglobin Level >12.0g/dL (RPA/AMA PCPI):** Percentage of calendar months within a 12-month period during which a hemoglobin (Hgb) is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis [HD] or peritoneal dialysis [PD]) who are also receiving ESA therapy and have a Hgb level >12.0g/dL.

*Comment:* KCP supports this measure for public reporting and payment.

c. **NQF 1667 Pediatric ESRD Patients Receiving Dialysis with Hgb Level <10g/dL (RPA/AMA PCPI):** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving HD or PD have a Hgb level <10g/dL.

*Comment:* KCP supports this measure for public reporting.

d. **NQF 1633 Blood Pressure Management (RPA/AMA PCPI):** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving RRT) and proteinuria with a blood pressure <130/80mmHg OR >130/80mmHg with a documented plan of care.

*Comment:* KCP supports this measure for public reporting.

e. **NQF 1668 Laboratory Testing (Lipid Profile) (RPA/AMA PCPI):** Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4, or 5, not receiving RRT) who had a fasting lipid profile performed at least once within a 12-month period.

*Comment:* KCP supports this measure for both public reporting and payment.

f. **NQF 0249 HD Adequacy CPM III—Minimum Delivered HD Dose (CMS):** Percentage of adult (>18 years old) patients in the sample for analysis who have been on HD for 6 months or more and dialyzing thrice weekly whose average delivered dose of HD (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >1.2 during the study period.

*Comment:* KCP supports this measure for both public reporting and payment.

g. **NQF 0323 HD Adequacy—Solute (RPA/AMA PCPI):** Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving HD three times a week have a spKt/V ≥1.2

*Comment:* KCP supports this measure for both public reporting and payment.

h. **NQF 0318 PD Adequacy CPM III—Delivered Dose of PD Above Minimum (CMS):** Percentage of adult (>18 years old) PD patients whose delivered PD dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the 4-month study period.

*Comment:* KCP supports this measure for both public reporting and payment.

i. **NQF 0321 PD Adequacy—Solute (RPA/AMA PCPI):** Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving PD who have a total Kt/V ≥1.7 per week measured once every 4 months.

*Comment:* KCP supports this measure for both public reporting and payment.

j. **NQF 0255 Measurement of Serum Phosphorus Concentration (CMS):** Percentage of all adult (>18 years old) PD and HD patients included in the sample for analysis with serum phosphorus measured at least once within the month.

*Comment:* KCP previously supported this measure; however, evidence provided by both small and large dialysis organizations within KCP indicate that performance on this
measure averages $\geq 97\%$. Given the minimal room for continued improvement, KCP recommends that the measure be moved to NQF reserve status.

k. **NQF 0251 Vascular Access—Functional AVF or AV Graft or Evaluation by Vascular Surgeon for Placement (KCQA):** Percentage of ESRD patients aged 18 years and older receiving HD during the 12-month reporting period and on dialysis $\geq 90$ days who (1) have a functional AVF [defined as two needles used or a single-needle device]; (2) have a functional AV graft; 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:* KCP supports this measure for public reporting.

l. **NQF 0256 HD Vascular Access—Minimizing Use of Catheters as Chronic Dialysis Access (CMS):** Percentage of patients on maintenance HD during the last HD treatment of the study period with a chronic catheter continuously for 90 days or longer prior to the last HD session.

*Comment:* KCP supports this measure for both public reporting and payment.

m. **NQF 0257 HD Vascular Access—Maximizing Placement of AVF (CMS):** Percentage of patients on maintenance HD during the last HD treatment of the month using an autogenous AVF with two needles.

*Comment:* KCP supports this measure for public reporting only. KCP recognizes the importance of appropriate vascular access selection and commends NQF for its ongoing work in this area. However, KCP believes that continued emphasis on maximizing fistula use does not reflect current evidence indicating that AV grafts are an acceptable alternative to fistulas and that the emphasis should be placed on maximizing permanent accesss — i.e., fistulas and grafts — and minimizing catheter use.

III. **Measures Not Recommended by NQF**
In addition to the measures just noted, KCP offers the following comments on the KCQA facility patient education measure that was not recommended by the Steering Committee. Specifically, we note that the NQF report indicated there was a “lack of clear consensus” on this measure (12 N, 10 Y). KCP strongly urges its reconsideration and that it be advanced for consideration and voting by all NQF Members.

a. **NQF 0324 Patient Education Awareness—Facility Level (KCQA):** ESRD patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including HD, PD, home HD, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.

*Comment:* KCP supports this measure for public reporting and recommends that it be advanced to the voting phase. While the NQF Steering Committee expressed concerns that the measure does not address the quality of the education provided or patient comprehension of what was taught, KCP stresses that the sole intent of this measure is to ensure that all ESRD patients are being educated on all renal replacement therapy modalities on an annual basis, as is consistent with the Conditions for Coverage. KCP recognizes that patient comprehension and the quality of the education provided are important issues, but notes that expert opinion and a growing body of peer-reviewed evidence indicate that focus on patient education can dramatically improve outcomes for chronic dialysis patients— even when there is not a separate assessment of patient comprehension or the quality of education. For instance, *using standardized, readily available materials*, individuals participating in a recent national predialysis treatment
options program (TOPs) were found to more frequently select home dialysis, had lower catheter rates, and had half the 90-day mortality risk when compared with patients not participating.\textsuperscript{1} As such, KCP maintains that this measure, as currently specified, is a critical and valuable component of the NQF ESRD measure set.

Additionally, while the NQF Steering Committee questioned whether the Standard Dialysis Facility Surveys required by CMS are sufficient to ensure that patient education is occurring on a yearly basis, KCP notes that CMS policy requires only that the time interval between surveys at any one facility be no more than 3.5 years,\textsuperscript{2,3} and that 19 states were unable to meet this requirement in 2009.\textsuperscript{4}

Likewise, Medicare data indicate that as of October 2010, one in ten facilities hadn’t had a top-to-bottom check in at least five years, and approximately 250 facilities hadn’t had a full recertification inspection in seven years or more.\textsuperscript{3} KCP also notes that the In-Center Hemodialysis CAHPS survey was cited as a better way to assess patient experience with education. We note that this instrument also does not assess comprehension; moreover, the construction of items related to modality options is not clearly distinguished.

Finally, the NQF Steering Committee stated that it believes there is no evidence that the measure will be widely implemented and used if endorsed. KCP notes, however, that as the measure has been included in CMS’s list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008, the data elements are in fact ultimately intended for collection via CROWNWeb and thus would be widely used.

IV. \textbf{Recommendations for Future Measure Development}
KCP appreciates and supports the NQF Steering Committee’s thoughtful recommendations for future measure development in the area of dialysis adequacy. In addition, KCP suggests that the following topics be prioritized in future measure development efforts:

- Bone and mineral metabolism;
- Dialysis treatment time;
- Patient education comprehension; and
- Timely referral of CKD Stage 4 patients to vascular surgeons for catheter reduction.

V. \textbf{Summary}
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 (lmgon@msn.com or 203.298.0567) if you have any questions.

\begin{itemize}
\item \textsuperscript{2} CMS. Timelines for Patient Assessment/Plan of Care, Version 1.3. Available at: www.esrdnetwork18.org. Accessed September 7, 2011.
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Sincerely,

Abbott Laboratories
Affymax
American Kidney Fund
American Nephrology Nurses’ Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
sanofi-aventis
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.