



AAHPM Comments submitted to the National Quality Forum on
National Voluntary Consensus Standards for End Stage Renal Disease
Submitted March 22, 2011

contact: Dale Lupu, PhD, dlupu@daleviewassociates.com

National Voluntary Consensus Standards for End Stage Renal Disease

The American Academy of Hospice and Palliative Medicine supports the eleven new measures, particularly noting that they are a step forward because they include pediatric patients in measures of dialysis adequacy and complications. However, even with these new measures, the list of NQF-endorsed measures for ESRD is still lacking in measures that robustly address the palliative care needs of ESRD patients as outlined in current guidelines.ⁱ We strongly recommend that NQF note this gap and develop a strategy for addressing it in future work.

Ample evidence shows that ESRD has a high mortality rateⁱⁱ, multiorgan dysfunction syndromeⁱⁱⁱ, symptom burden,^{iv v vi} and incidence of depression^{vii} and that life-threatening complications and sudden death are common occurrences for both pediatric^{viii ix x} and adult patient populations.^{xi} Furthermore, end-of-life decisions are frequently made after the patient has lost decisional capacity.^{xii} Current clinical guidelines for shared-decision making concerning withdrawal of dialysis in both adults and children specify using advance care planning, integrating palliative care, and addressing symptoms and disease burden.¹ Quality measures that address these areas are needed so that clinical settings can assess their progress in delivering the care that meets the guidelines. To address both the high symptom burden and the high mortality rate, quality care of patients with ESRD should include:

1. assessment and treatment of common symptoms including (in order of prevalence) fatigue, insomnia, cramping, pruritus (itching), neuropathic pain, depression, nausea and vomiting;
2. advance care planning on at least an annual basis, including prognosis and goals of care, appointment of health care proxy, living will, resuscitation wishes; discussion of circumstances under which the patient would want dialysis stopped, and where the patient would like to spend the last days of life;

3. assessment of multiple quality of life domains, as measured in the KDQOL-36—currently endorsed by the NQF, but only for adults
4. utilization of a holistic interdisciplinary team to address quality of life needs and concerns that may be identified by the KDQOL-36 or other means
5. appropriate utilization of hospice and palliative care for patients who stop dialysis and as concurrent care along with dialysis for patients who have poor prognosis such as advanced cancer.

The current and proposed measures target the adequacy of dialysis and assessment of complications (anemia, hypercalcemia, hospitalization and bacteremia). However, none of the 11 recommended measures, nor any of the rest of the 32 measures that were initially considered, address any essential domains of palliative care (e.g. quality of life, advance care planning, symptom assessment or management, or bereavement support.)

Among the 25 quality measures already endorsed in 2008, only four address a domain of palliative care. However, these are limited. They exclude pediatric patients, and they do not address many areas of palliative care. The existing measures applicable to palliative care needs are:

- 0324 Patient education awareness –facility level (excludes patient s <18 years old and calls for a documented discussion at least once every 12-month reporting year about renal replacement modalities including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no renal replacement therapy.)
- 0320 Patient education awareness-individual clinician level (same as above)
- 0260 Assessment of Health-Related Quality of Life (Physical and Mental Functioning)-facility level (excludes patient s < 18 years old and calls for patients to complete a Kidney Disease Quality of Life KDQOL-36 document at least once a year that includes symptoms, functioning and other QOL domains important for palliative care.)
- 0258 Consumer Assessment of Healthcare Providers and Systems (CAHPS) In-center Hemodialysis Survey-facility level (excludes patients < 18 years old and measures responses to 57 questions about quality of care provided to patients at in-center hemodialysis units-including communication and information received.)

These 11 new standards are a step forward because they include pediatric patients in measures of dialysis adequacy and complications, but they do not address the gap that exists from the exclusion of pediatric patients from the four existing measures with

relevance to palliative care outlined above. We recommend that future work include measures that address *the* palliative care aspects of the applicable ESRD guidelines.

- i Renal Physicians Association (RPA). Shared decision-making in the appropriate initiation of withdrawal from dialysis. 2nd ed. Rockville (MD): Renal Physicians Association (RPA); 2010 Oct.
- ii Data from the Prospective Pediatric Continuous Renal Replacement Therapy (ppCRRT) Registry Group revealed 58% survival, with worse prognosis for patients with liver failure/transplant (31%), pulmonary disease/transplant (45%) and stem cell transplant (45%). (Symons JM, Chua AN, Somers MJ 2007)
- iii Goldstein SL, Somers MJG, Baum M a, Symons JM, Brophy PD, Blowey D, et al. Pediatric patients with multi organ dysfunction syndrome receiving continuous renal replacement therapy. *Kidney international*. 2005 Feb ;67(2):653-8.
- iv Poppel DM, Cohen LM, Germain MJ, The Renal Palliative Care Initiative. *J Pal Med*, 2003; 6:321-326
- v Strid, et al. The prevalence of gastrointestinal symptoms in patients with chronic renal failure is increased and associated with impaired psychological general well-being. *Nephrol Dial Transplant*, 2002; 17:1434-1439
- vi Fukuhara, et al, Health-related quality of life among dialysis patients on three continents: the Dialysis Outcomes and Practice Patterns Study. *Kidney Int*, 2003; 64:1903-1910
- vii Lopes, et al, Depression as a predictor of mortality and hospitalization among hemodialysis patients in the United States and Europe. *Kidney Int*, 2002; 62:199-207
- viii Symons JM, Chua AN, Somers MJ et al. Demographic characteristics of pediatric continuous renal replacement therapy: a report of the prospective pediatric continuous renal replacement therapy registry. *Clin J Am Soc Nephrol*. 2007 Jul;2(4):732-8.
- ix Flores FX, Brophy PD, Symons JM, Fortenberry JD, Chua AN, Alexander SR, et al. Continuous renal replacement therapy (CRRT) after stem cell transplantation. A report from the prospective pediatric CRRT Registry Group. [Internet]. *Pediatric nephrology* (Berlin, Germany). 2008 Apr ;23(4):625-30.
- x Rajasekaran S, Jones DP, Avent Y, Shaffer ML, Elbahlawan L, Henderson N, et al. Outcomes of hematopoietic stem cell transplant patients who received continuous renal replacement therapy in a pediatric oncology intensive care unit. [Internet]. *Pediatric critical care medicine*. 2010 Nov ;11(6):699-706.
- xi Herzog, Cardiac arrest in dialysis patients: approaches to alter an abysmal outcome. *Kidney Int*, 2003; 63:S197-200
- xii Cohen, et al, Dialysis discontinuation and palliative care. *AJKD*, 2000; 36:140-144

April 15, 2011

National Quality Forum
601 13th Street NE
Suite 500 North
Washington DC 20005

RE: Draft National Voluntary Consensus Standards for End Stage Renal Disease (ESRD)
2010: A Consensus Report

To whom it may concern:

On behalf of the American Society of Nephrology (ASN), a not-for-profit organization of more than 12,000 physicians and scientists dedicated to promoting excellence in the care of patients with kidney disease, thank you for the opportunity to provide comment regarding the Draft National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report. Foremost among ASN's concerns is helping its members provide the highest quality of care possible to patients with kidney disease.

General comments

ASN supports the National Quality Forum's (NQF) commitment to improving the quality of life for patients with ESRD by identifying measures of the quality of care for ESRD that are suitable for public reporting and quality improvement programs. ASN was pleased to be represented on the NQF Steering Committee by ASN member Jeffrey Berns, MD, FASN, of the University of Pennsylvania School of Medicine. ASN appreciates the work of the Steering Committee and commends their efforts to identify Consensus Standards. The society thanks NQF for the opportunity to comment on the draft report at this time.

Comments on measures recommended

NQF recommended 11 measures for endorsement as voluntary consensus standards suitable for public reporting and quality improvement. ASN generally supports these recommendations, with the qualifications described below. However, the society wishes to note that at this time, scant high-quality evidence exists to support the majority of these measures. Developing new performance measures based on intermediate outcomes and retrospective observational studies will not necessarily improve care for patients with ESRD. Indeed, such measures could potentially lead to unintended adverse consequences or increased costs of care without improving meaningful, patient-centered outcomes. In the future, these measures should be replaced by new measures as scientifically validated performance targets are developed.

It is ASN's understanding that national voluntary consensus quality measures endorsed by NQF could potentially be used by the Centers for Medicare and Medicaid Services (CMS) as measures in the ESRD Quality Incentive Program (QIP) for value-based purchasing. Although based on the currently available evidence ASN does generally support the measures as

described above, the society has serious reservations about their suitability for a financially-incentivized measure due to the insufficiency of scientifically-validated evidence. Furthermore, ASN believes that it is imperative that any new measures CMS considers for the QIP must be subjected to rulemaking with a public comment period.

- **Dialysis Adequacy**

1418: Frequency of adequacy measurement for pediatric hemodialysis patients (CMS): Percentage of all pediatric (less than 18 years) 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 supports this measure.

1421: Method of adequacy measurement for pediatric hemodialysis patients (CMS): Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.
ASN supports this measure.

1423: Minimum spKt/V for pediatric hemodialysis patients (CMS): Percentage of all pediatric (less than 18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a pKt/V greater than or equal to 1.2.
ASN supports this measure.

- **Nutrition**

1425: Measurement of nPCR for pediatric hemodialysis patients (CMS) (Time-Limited): Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.
ASN supports this measure.

- **Anemia**

1424: Monthly hemoglobin measurement for pediatric patients (CMS): Percentage of all pediatric (less than 18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin.
ASN supports this measure.

1430: Lower limit of hemoglobin for pediatric patients (CMS): Percentage of pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients, with ESRD greater than or equal to 3 months, who have a mean hemoglobin less than 10 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation.
ASN supports this measure.

1433: Use of iron therapy for pediatric patients (CMS) (Time-Limited): 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 serum ferritin concentration was less than 100 ng/ml and TSAT less than 20% who received IV iron or were prescribed oral iron within the following three months.
ASN supports this measure.

- **Fluid Management**

1438: Periodic assessment of post-dialysis weight by nephrologists (CMS) (Time-Limited): The proportion of patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month, irrespective of whether or not a change in post dialysis weight prescription was made.

ASN recognizes the importance of fluid management, but does not support this measure at the facility level. ASN suggests that this measure should be addressed at the clinician level.

Furthermore, as currently written the specifications require a “prescription.” ASN suggests that this be modified to an “assessment,” as indicated in the description. A new prescription may not be necessary after an assessment.

- **Mineral Metabolism**

1454: Proportion of patients with hypercalcemia (CMS): Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL

ASN supports this measure.

- **Hospitalization**

1463: Standardized hospitalization ratio for admissions (CMS): Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.

ASN concurs that hospitalization is a crucial aspect of ESRD care to measure. However, as currently written, the measure encompasses all admissions. ASN suggests that the language be modified to specify a “Risk-adjusted standardized hospitalization ratio for admissions for dialysis access-related infections and fluid overload.” If modified, ASN would support this measure.

- **Infection**

1460: National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC): Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.

ASN supports this measure.

Comments on measures not recommended

In general, ASN concurs with NQF’s proposal not to recommend the remaining measures considered. ASN is aware, however, that some in the nephrology community have suggested that NQF reconsider measure 1427 “Adult dialysis patients—serum phosphorus greater than 6 mg/dL.” (Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.) ASN recognizes that monitoring patients’ serum phosphate levels is an important component of high-quality patient care.

However, based upon currently available evidence, ASN does not recommend that NQF reconsider measure 1427 “Adult dialysis patients—serum phosphorus greater than 6 mg/dL.”

Importantly, serum phosphorus is a surrogate marker. Serum phosphorus control is a function of several components, and is strongly influenced by patient behavior—particularly with respect to diet. ASN is concerned that establishing a quality measure for serum phosphorus could potentially result in the unintended consequence of biasing some providers against caring for socioeconomically disadvantaged populations, as their nutritional options are more limited and they may not have access to the array of available phosphate binders. Additionally, blacks on

dialysis tend to have higher serum phosphorus concentrations compared with whites, in part owing to endogenous hyperphosphatemia from more severe secondary hyperparathyroidism. It would also be challenging to apply this measure for patients who dialyze at home.

Moreover, ASN believes that there is insufficient evidence that 6 mg/dl is in fact the most appropriate threshold, as well as insufficient evidence that lowering phosphorus translates into improved outcomes in terms of cardiovascular or bone disease outcomes or mortality. ASN also notes that there is a relatively low relative risk associated with hyperphosphatemia at the 6mg/dL level. Treating hyperphosphatemia involves expense, patient inconvenience, pill burden, dietary limitations, and drug adverse effects. In the absence of evidence, concern also exists that overly stringent nutritional restrictions for the control of serum phosphorus may contribute to the much-dreaded malnutrition that many patients on dialysis develop. In the absence of demonstrated benefit of treatment, ASN believes this measure is not a reasonable quality metric and should not be reconsidered by NQF. Serum phosphorus maintenance—as well as the other measures recommended for endorsement—are, however, areas ASN believes strongly would benefit from further investigation; randomized clinical trials as well as comparative effectiveness research would be of great value to the nephrology community.

Again, thank you for your time and consideration. The society is grateful for the opportunity to provide comment to NQF and would welcome the opportunity to contribute in any capacity in future quality measure selection or development. ASN would also be pleased to discuss these comments with the CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

A handwritten signature in blue ink that reads "Joseph V. Bonventre". The signature is fluid and cursive, with the first name "Joseph" and last name "Bonventre" clearly legible.

Joseph V. Bonventre, MD, PhD, FASN
President, American Society of Nephrology



APR 18 2011

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April 13, 2010

Lauren Richie

Project Manager, Performance Measures

National Quality Forum

601 13th Street NW, Suite 500 North

Washington, D.C. 20005

Re: Comments on “National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report”

Dear Lauren,

As one of the leading providers of renal care in the US and an organization driven to quality outcomes, DaVita appreciates the opportunity to comment on the NQF's Consensus Standards for ESRD, dated March 25, 2011

We first commend NQF on its ability to review the 44 measures submitted for review and reduce them to a meaningful number. Based on our own experiences with composite quality metrics, we have found that focusing on a minimal number of quality measures is the best path forward to improve quality.

The NQF is recommending the following:

Adult Measures

- Periodic assessment of post-dialysis weight by nephrologists (Time-limited) (CMS)
- Proportion of patients with hypercalcemia (CMS)
- Standardized hospitalization ratio(SHR) for admissions (CMS)
- National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC)

Pediatric Measures

- Frequency of adequacy measurement for pediatric hemodialysis patients (CMS)
- Method of adequacy measurement for pediatric hemodialysis patients (CMS)
- Minimum spKt/V for pediatric hemodialysis patients (CMS)
- Measurement of nPCR for pediatric hemodialysis patients (Time-limited) (CMS)
- Use of iron therapy for pediatric patients (Time-limited) (CMS)

Monthly hemoglobin measurement for pediatric patients (CMS)
Lower limit of hemoglobin for pediatric patients (CMS)

DaVita is in agreement with the majority of the measures but does have some comments.

- First, we are concerned about the mechanics and details of the SHR measure. While such a measure is good to track, we would advocate that the predictive equation used to calculate the predicted hospitalization rate in the denominator of the measure definition be subject to peer review or third party validation. We note that the very same hospitalization measure for hospitals has recently been subject to this exact disclosure and published in the peer review literature. Without the same degree of review, the ratio lacks meaning and validity
- Secondly, we endorse the Center for Disease Control's NHSN BSI measure. This measure, stratified by vascular access type will allow the first meaningful look into the prevalence of healthcare acquired infections (HAI). We prefer this definition over other possible infection measures. Specifically, while the presence of infection has been recorded on the dialysis claim form since July 2010 via the V8/V9 modifier, there is much ambiguity around the specification being used to apply this modifier, nullifying its use as a performance measure.
- Lastly, we firmly believe that a phosphorus measure is necessary. The committee spent time debating the validity of such a measure and the strength of the evidence. However, we believe that the first part of the discussion is moot when face with reality. From a practical standpoint, CMS will require a phosphorus measure with the inclusion of orals in the ESRD payment system in 2014, and has already said so publically in the recently released GAO report. As such we urge the committee to reconsider its decision and approve the submitted phosphorus measure. While the evidence is not concrete, it stands on par with the evidence supporting the other ESRD measures agreed to by the committee.

Globally, we believe that future and exploratory measure development and collection needs to proceed with a needed data feasibility step. While this was the intent of the Data Technical Expert Panel (DTEP), the valuable input from this part of the measure development process was not heeded, and the 44 measures submitted reflected only the initial brainstorming of the Clinical Technical Expert panel (CTEP).

We articulate our more detailed comments below, concentrating on the adult measures.

Comment on Individual Measures

Standardized hospitalization ratio for admissions (CMS)

Hospitalization rate reflects a combination of factors. Hospitalization may occur due to the patient, provider or disease. Thus, unlike in the hospital setting, quality in the dialysis unit may not be directly reflected in the admission rate for that facility. Nonetheless, there may be value in tracking this measure as a metric, but only if the mathematics used are robust, and allow appropriate adjustment for differences in case mix. At a minimum, such a measure should also focus on the year over year improvement as the current QIP methodology already does.

The currently proposed measure seeks to create a ratio of the actual hospitalization rates to a predicted hospitalization rate using only claims based data. While such reporting has been disclosed through the Dialysis Facility (DFC) and Dialysis Facility Report (DFR) process, there has been limited disclosure around the mathematical equations for the predicted hospitalization rate that drives this metric. To date, the predicted hospitalization equation and methodology has not been subject to peer review or validation despite its use today.

The approach used for the ESRD SHR and SMR contrasts sharply with the peer reviewed process used for the predicted hospitalization rate used for the SHR ratio for hospitals. (Krumholtz, Circ Cardiovasc Qual Outcomes, March 2011) We urge the NQF to recommend a peer review and validation process for the SHR metric prior to implementation.

Further, it is inevitable that the detailed clinical information available via CROWNWeb can only strengthen the predictive power of any modeling. Therefore, NQF may wish to ask the measure developers to consider this richer data set for modeling purposes before needlessly settling on the claims based data only.

National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC)

As mentioned above, we support the NHSN BSI Measure as the recommended by the committee. Using this metric stratified by vascular access type will provide a meaningful metric to support HAI efforts. This metric is superior in terms of sensitivity and specificity the currently claims based V8/V9 measures.

Phosphorous Measures

While a phosphorous measure was submitted for consideration (percentage of patients with phosphorus less than 6 mg/dl), this was rejected by the committee. The rationale for this rejection seemed to be the validity of having such a measure or not and the lack of strong, direct evidence supporting the importance of such a measure.

This may make sense from an academic perspective, but not from a policy perspective. Oral medications affecting serum phosphorous will be included in the bundle by January 2014. CMS included anemia metrics when ESAs were included in the bundle. Following this logic, a phosphorous metric be desired when phosphorus binders are included. In a recent GAO report, CMS has already said it will likely move forward with a non NQF endorsed metric for phosphorus for this very reason.

Therefore, we urge the NQF to reconvene its committee to discuss and debate not if a measure is appropriate (as that is a foregone conclusion) but rather approve the existing measure. The level of evidence supporting a phosphorous measure such as less than 6 mg/dl is observational and retrospective. So too are the data supporting many of the other measures listed for ESRD. The NQF panel should be able to have such a discussion and make a recommendation that will serve as an NQF endorsed recommendation for CMS's inevitable future CPM.

Periodic assessment of post-dialysis weight by nephrologists (Time-limited)

We agree that fluid related overload is a preventable condition that requires a metric. As such, the periodic assessment of post dialysis weight by nephrologists is a reasonable measure. The

data is available in electronic health records today and thus meets the data feasibility criteria. However, paralleling our discussion around the strength of evidence for the phosphorous measure, we are not aware of any data, either prospective or retrospective which supports the validity of this measure.

Proportion of patients with hypercalcemia

DaVita is supportive of the proposed hypercalcemia metric. We believe that the recommendation is consistent with the prevailing community standard and the literature, and as such offer no supplemental comments

Pediatric Measures

Similarly, DaVita believes that the pediatric measures are important, supported by the literature and the pediatric experts and offers no comments for the measures covered by this domain.

Conclusion

DaVita is committed to the relentless pursuit of quality. We therefore are supportive of the recommendations of the NQF in this area with the exceptions and requested clarifications listed above.

As we have outlined the SHR measure methodology requires peer review or external, third party validation before it can be considered as a performance metric. Next, the NHSN BSI measure should be used as it is superior to any claims based measure using V8 and V9 modifier code. . Lastly, and most importantly, the NQF needs to reconvene its expert committee to endorse the submitted phosphorous measure. With the inclusion of oral drugs in the bundled payment system in 2014, there is now question that CMS will be forced to implement such a measure. That measure will be implemented with or without NQF endorsement, but we urge the NQF to consider this inevitability in its deliberations and approve the current measure.

We are supportive of the processes that lead to the development of these measures with one notable exception. Measures need to be subjected to data feasibility BEFORE submission the NQF. Without this needed step, the NQF will receive a large number of measures unsuitable for use as was the case in this cycle of measure development and review. CMS and NQF need to work collaboratively to ensure that this does not happen again.

Sincerely,



Allen R. Nissenson, M.D.
Chief Medical Officer - OCMO

April 11, 2011

National Quality Forum
Lauren Richie
601 13th Street NW
Suite 500 North
Washington, D.C. 20005

Via Email: esrd@qualityforum.org

Re: Pre-voting review for *National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report*

Dear Lauren Richie,

Dialysis Patient Citizens (DPC) is pleased to provide comments to the National Quality Forum (NQF) on the pre-voting review for *National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report*. As America's largest dialysis patient organization, DPC seeks to ensure that the patient's point of view is heard and considered by policy makers on a wide variety of issues so continued progress may be made in the quality of care and life for dialysis patients. We are pleased that Congress and the Centers for Medicare and Medicaid Services (CMS) have taken steps to develop a Quality Incentive Program (QIP) that seeks to align incentives with patient outcomes. We believe that the quality measures included in this program should, above all, be patient-centered, reflective of health outcomes for all dialysis patients regardless of the treatment modality they choose (i.e. in-center hemodialysis, home hemodialysis and peritoneal dialysis) and target levels that will ensure patients do not just meet adequate standards, but can live good quality lives. We know that a diagnosis of End Stage Renal Disease (ESRD) does not mean the end of life; it simply means the end of kidney function. With proper health care and self-management, dialysis patients can lead long, productive lives. An NQF endorsement is important to the decision making at CMS in regards to the selection of future measures for the QIP. It is with this frame of mind that we respectfully issue the following comments on this NQF report.

DPC supports the goal to develop and endorse more measures reflective of patient outcomes. We would like to issue our general support for the measures recommended for endorsement by the NQF steering committee and particularly would like to highlight those that are most closely aligned with patient outcomes and those where we have additional suggestions for slight modification of the measure.

1454 Upper Limit for Total Uncorrected Serum Calcium

Bone and mineral measures are extremely critical to dialysis patients. Patients are currently measured on these areas and in many cases receive not only the lab results, but also a separate progress report educating them on how well they are doing in keeping their calcium and phosphorus at appropriate levels. We recognize this is a measure that not only requires

proper care delivery, but also education for patients, as they have a role in managing bone and mineral metabolism through maintaining proper diet and medication adherence. DPC supports the upper limit for serum calcium because we recognize high levels of calcium can cause calcification of arteries and other cardiovascular complications for dialysis patients. Additionally, we believe with the payment changes under the Medicare program for ESRD and medications being moved into a bundled payment system, this measure is of particular importance and should be included in the QIP to ensure patients receive optimal quality care.

1460 National Healthcare Safety Network (NHSN) Bloodstream Infection Measure

Infections are the second leading cause of death in dialysis patients falling just slightly behind cardiovascular disease. We strongly support the Steering Committee's recommendation for endorsement and believe this is a crucial measure to be included in the future years of the QIP.

1463 Standardized Hospitalization Ratio (SHR) for Admissions

While we are supportive of this measure we feel it is important to note that dialysis facilities currently do not provide the totality of patients' care, and there are factors not currently treated at the dialysis facility that could lead to hospitalization of the patient. We feel this measure should be modified to measure hospitalizations related to the outcomes of dialysis treatment.

While in general we are supportive of the measures the steering committee is recommending, we are particularly concerned the Committee did not include **measure 1427 Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl**. As mentioned under our comments for the upper serum calcium measure, bone and mineral measures are important to evaluating patients' health. Regulating patients' bone and mineral metabolism is vital to preventing co-morbidities such as increased bone fractures, cardiovascular complications, calcification of arteries and parathyroidectomies. Dialysis does not adequately remove phosphorus from the blood, and phosphorus levels cannot be completely controlled by diet alone because, in order to maintain proper albumin, patients must eat plenty of protein. Phosphorus is commonly found in most sources of protein, and for this reason, patients are routinely prescribed phosphorus binders to remove excessive levels of phosphorus.

We are respectful of the challenges in applying and finding data and research to support the impact that outcome measures have on mortality and co-morbidities, but believe where data and research are lacking that deference to widely used clinical practices, shown to cause no harm to patients, should be considered until more definitive scientific data becomes available. Since Medicare has moved to a bundled reimbursement for dialysis care, it is important that quality measures are in place to ensure patients receive optimal care. We believe a safer route to ensure patients continue to receive proper treatment is to endorse the serum phosphorus levels below 6mg/dl measure, which is clearly an established standard of care and shows no evidence of causing harm to patients. Since the steering committee could not come to a consensus on this measure, we suggested as an alternative to a full three-year endorsement, it may be appropriate to endorse it as time-limited allowing more research to be conducted.

Not endorsing the measure could send the signal that this measure is not of clinical importance and may have negative consequences for patient care.

We thank the steering committee for its work on the ESRD measures submitted and are particularly pleased the committee makeup included dialysis patients who can attest to their experience with the delivery of quality care. This consumer perspective is of great importance, as all patients should be actively engaged with health care decisions both when it comes to their own health decisions and when it comes to policy matters that influence care delivery.

Respectfully,



Nancy L. Scott
Board President

April 15, 2011

National Quality Forum
601 13th Street NE
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Washington DC 20005

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2010: A Consensus Report

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1421: Method of adequacy measurement for pediatric hemodialysis patients (CMS): Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.
ASN supports this measure.

1423: Minimum spKt/V for pediatric hemodialysis patients (CMS): Percentage of all pediatric (less than 18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a pKt/V greater than or equal to 1.2.
ASN supports this measure.

- **Nutrition**

1425: Measurement of nPCR for pediatric hemodialysis patients (CMS) (Time-Limited): Percentage of pediatric (less than 18 years old) in-center HD patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.
ASN supports this measure.

- **Anemia**

1424: Monthly hemoglobin measurement for pediatric patients (CMS): Percentage of all pediatric (less than 18 years) hemodialysis and peritoneal dialysis patients who have monthly measures for hemoglobin.
ASN supports this measure.

1430: Lower limit of hemoglobin for pediatric patients (CMS): Percentage of pediatric (less than 18 years old) hemodialysis and peritoneal dialysis patients, with ESRD greater than or equal to 3 months, who have a mean hemoglobin less than 10 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation.
ASN supports this measure.

1433: Use of iron therapy for pediatric patients (CMS) (Time-Limited): 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 serum ferritin concentration was less than 100 ng/ml and TSAT less than 20% who received IV iron or were prescribed oral iron within the following three months.
ASN supports this measure.

- **Fluid Management**

1438: Periodic assessment of post-dialysis weight by nephrologists (CMS) (Time-Limited): The proportion of patients who have documentation of receiving a new post-dialysis weight prescription from a nephrologist in the reporting month, irrespective of whether or not a change in post dialysis weight prescription was made.

ASN recognizes the importance of fluid management, but does not support this measure at the facility level. ASN suggests that this measure should be addressed at the clinician level.

Furthermore, as currently written the specifications require a “prescription.” ASN suggests that this be modified to an “assessment,” as indicated in the description. A new prescription may not be necessary after an assessment.

- **Mineral Metabolism**

1454: Proportion of patients with hypercalcemia (CMS): Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL

ASN supports this measure.

- **Hospitalization**

1463: Standardized hospitalization ratio for admissions (CMS): Risk-adjusted standardized hospitalization ratio for admissions for dialysis facility patients.

ASN concurs that hospitalization is a crucial aspect of ESRD care to measure. However, as currently written, the measure encompasses all admissions. ASN suggests that the language be modified to specify a “Risk-adjusted standardized hospitalization ratio for admissions for dialysis access-related infections and fluid overload.” If modified, ASN would support this measure.

- **Infection**

1460: National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC): Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient-months.

ASN supports this measure.

Comments on measures not recommended

In general, ASN concurs with NQF’s proposal not to recommend the remaining measures considered. ASN is aware, however, that some in the nephrology community have suggested that NQF reconsider measure 1427 “Adult dialysis patients—serum phosphorus greater than 6 mg/dL.” (Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.) ASN recognizes that monitoring patients’ serum phosphate levels is an important component of high-quality patient care.

However, based upon currently available evidence, ASN does not recommend that NQF reconsider measure 1427 “Adult dialysis patients—serum phosphorus greater than 6 mg/dL.”

Importantly, serum phosphorus is a surrogate marker. Serum phosphorus control is a function of several components, and is strongly influenced by patient behavior—particularly with respect to diet. ASN is concerned that establishing a quality measure for serum phosphorus could potentially result in the unintended consequence of biasing some providers against caring for socioeconomically disadvantaged populations, as their nutritional options are more limited and they may not have access to the array of available phosphate binders. Additionally, blacks on

dialysis tend to have higher serum phosphorus concentrations compared with whites, in part owing to endogenous hyperphosphatemia from more severe secondary hyperparathyroidism. It would also be challenging to apply this measure for patients who dialyze at home.

Moreover, ASN believes that there is insufficient evidence that 6 mg/dl is in fact the most appropriate threshold, as well as insufficient evidence that lowering phosphorus translates into improved outcomes in terms of cardiovascular or bone disease outcomes or mortality. ASN also notes that there is a relatively low relative risk associated with hyperphosphatemia at the 6mg/dL level. Treating hyperphosphatemia involves expense, patient inconvenience, pill burden, dietary limitations, and drug adverse effects. In the absence of evidence, concern also exists that overly stringent nutritional restrictions for the control of serum phosphorus may contribute to the much-dreaded malnutrition that many patients on dialysis develop. In the absence of demonstrated benefit of treatment, ASN believes this measure is not a reasonable quality metric and should not be reconsidered by NQF. Serum phosphorus maintenance—as well as the other measures recommended for endorsement—are, however, areas ASN believes strongly would benefit from further investigation; randomized clinical trials as well as comparative effectiveness research would be of great value to the nephrology community.

Again, thank you for your time and consideration. The society is grateful for the opportunity to provide comment to NQF and would welcome the opportunity to contribute in any capacity in future quality measure selection or development. ASN would also be pleased to discuss these comments with the CMS if it would be helpful. To discuss ASN's comments, please contact ASN Director of Policy and Public Affairs, Paul C. Smedberg, at (202) 416-0640 or at psmedberg@asn-online.org.

Sincerely,

A handwritten signature in blue ink that reads "Joseph V. Bonventre". The signature is fluid and cursive, with the first name "Joseph" and last name "Bonventre" clearly legible.

Joseph V. Bonventre, MD, PhD, FASN
President, American Society of Nephrology



APR 18 2011

Office of the Chief
Medical Officer (OCMO)

Allen R. Nissenson, MD
Chief Medical Officer

Mahesh Krishnan, MD
Stephen McMurray, MD
Robert Merrell, MD
John Moran, MD
Robert Provenzano, MD
John Robertson, MD
David B. Van Wyck, MD

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April 13, 2010

Lauren Richie

Project Manager, Performance Measures

National Quality Forum

601 13th Street NW, Suite 500 North

Washington, D.C. 20005

Re: Comments on “National Voluntary Consensus Standards for End Stage Renal Disease (ESRD) 2010: A Consensus Report”

Dear Lauren,

As one of the leading providers of renal care in the US and an organization driven to quality outcomes, DaVita appreciates the opportunity to comment on the NQF's Consensus Standards for ESRD, dated March 25, 2011

We first commend NQF on its ability to review the 44 measures submitted for review and reduce them to a meaningful number. Based on our own experiences with composite quality metrics, we have found that focusing on a minimal number of quality measures is the best path forward to improve quality.

The NQF is recommending the following:

Adult Measures

Periodic assessment of post-dialysis weight by nephrologists (Time-limited) (CMS)

Proportion of patients with hypercalcemia (CMS)

Standardized hospitalization ratio(SHR) for admissions (CMS)

National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC)

Pediatric Measures

Frequency of adequacy measurement for pediatric hemodialysis patients (CMS)

Method of adequacy measurement for pediatric hemodialysis patients (CMS)

Minimum spKt/V for pediatric hemodialysis patients (CMS)

Measurement of nPCR for pediatric hemodialysis patients (Time-limited) (CMS)

Use of iron therapy for pediatric patients (Time-limited) (CMS)

Monthly hemoglobin measurement for pediatric patients (CMS)
Lower limit of hemoglobin for pediatric patients (CMS)

DaVita is in agreement with the majority of the measures but does have some comments.

- First, we are concerned about the mechanics and details of the SHR measure. While such a measure is good to track, we would advocate that the predictive equation used to calculate the predicted hospitalization rate in the denominator of the measure definition be subject to peer review or third party validation. We note that the very same hospitalization measure for hospitals has recently been subject to this exact disclosure and published in the peer review literature. Without the same degree of review, the ratio lacks meaning and validity
- Secondly, we endorse the Center for Disease Control's NHSN BSI measure. This measure, stratified by vascular access type will allow the first meaningful look into the prevalence of healthcare acquired infections (HAI). We prefer this definition over other possible infection measures. Specifically, while the presence of infection has been recorded on the dialysis claim form since July 2010 via the V8/V9 modifier, there is much ambiguity around the specification being used to apply this modifier, nullifying its use as a performance measure.
- Lastly, we firmly believe that a phosphorus measure is necessary. The committee spent time debating the validity of such a measure and the strength of the evidence. However, we believe that the first part of the discussion is moot when face with reality. From a practical standpoint, CMS will require a phosphorus measure with the inclusion of orals in the ESRD payment system in 2014, and has already said so publically in the recently released GAO report. As such we urge the committee to reconsider its decision and approve the submitted phosphorus measure. While the evidence is not concrete, it stands on par with the evidence supporting the other ESRD measures agreed to by the committee.

Globally, we believe that future and exploratory measure development and collection needs to proceed with a needed data feasibility step. While this was the intent of the Data Technical Expert Panel (DTEP), the valuable input from this part of the measure development process was not heeded, and the 44 measures submitted reflected only the initial brainstorming of the Clinical Technical Expert panel (CTEP).

We articulate our more detailed comments below, concentrating on the adult measures.

Comment on Individual Measures

Standardized hospitalization ratio for admissions (CMS)

Hospitalization rate reflects a combination of factors. Hospitalization may occur due to the patient, provider or disease. Thus, unlike in the hospital setting, quality in the dialysis unit may not be directly reflected in the admission rate for that facility. Nonetheless, there may be value in tracking this measure as a metric, but only if the mathematics used are robust, and allow appropriate adjustment for differences in case mix. At a minimum, such a measure should also focus on the year over year improvement as the current QIP methodology already does.

The currently proposed measure seeks to create a ratio of the actual hospitalization rates to a predicted hospitalization rate using only claims based data. While such reporting has been disclosed through the Dialysis Facility (DFC) and Dialysis Facility Report (DFR) process, there has been limited disclosure around the mathematical equations for the predicted hospitalization rate that drives this metric. To date, the predicted hospitalization equation and methodology has not been subject to peer review or validation despite its use today.

The approach used for the ESRD SHR and SMR contrasts sharply with the peer reviewed process used for the predicted hospitalization rate used for the SHR ratio for hospitals. (Krumholtz, Circ Cardiovasc Qual Outcomes, March 2011) We urge the NQF to recommend a peer review and validation process for the SHR metric prior to implementation.

Further, it is inevitable that the detailed clinical information available via CROWNWeb can only strengthen the predictive power of any modeling. Therefore, NQF may wish to ask the measure developers to consider this richer data set for modeling purposes before needlessly settling on the claims based data only.

National Healthcare Safety Network (NHSN) bloodstream infection measure (CDC)

As mentioned above, we support the NHSN BSI Measure as the recommended by the committee. Using this metric stratified by vascular access type will provide a meaningful metric to support HAI efforts. This metric is superior in terms of sensitivity and specificity the currently claims based V8/V9 measures.

Phosphorous Measures

While a phosphorous measure was submitted for consideration (percentage of patients with phosphorus less than 6 mg/dl), this was rejected by the committee. The rationale for this rejection seemed to be the validity of having such a measure or not and the lack of strong, direct evidence supporting the importance of such a measure.

This may make sense from an academic perspective, but not from a policy perspective. Oral medications affecting serum phosphorous will be included in the bundle by January 2014. CMS included anemia metrics when ESAs were included in the bundle. Following this logic, a phosphorous metric be desired when phosphorus binders are included. In a recent GAO report, CMS has already said it will likely move forward with a non NQF endorsed metric for phosphorus for this very reason.

Therefore, we urge the NQF to reconvene its committee to discuss and debate not if a measure is appropriate (as that is a foregone conclusion) but rather approve the existing measure. The level of evidence supporting a phosphorous measure such as less than 6 mg/dl is observational and retrospective. So too are the data supporting many of the other measures listed for ESRD. The NQF panel should be able to have such a discussion and make a recommendation that will serve as an NQF endorsed recommendation for CMS's inevitable future CPM.

Periodic assessment of post-dialysis weight by nephrologists (Time-limited)

We agree that fluid related overload is a preventable condition that requires a metric. As such, the periodic assessment of post dialysis weight by nephrologists is a reasonable measure. The

data is available in electronic health records today and thus meets the data feasibility criteria. However, paralleling our discussion around the strength of evidence for the phosphorous measure, we are not aware of any data, either prospective or retrospective which supports the validity of this measure.

Proportion of patients with hypercalcemia

DaVita is supportive of the proposed hypercalcemia metric. We believe that the recommendation is consistent with the prevailing community standard and the literature, and as such offer no supplemental comments

Pediatric Measures

Similarly, DaVita believes that the pediatric measures are important, supported by the literature and the pediatric experts and offers no comments for the measures covered by this domain.

Conclusion

DaVita is committed to the relentless pursuit of quality. We therefore are supportive of the recommendations of the NQF in this area with the exceptions and requested clarifications listed above.

As we have outlined the SHR measure methodology requires peer review or external, third party validation before it can be considered as a performance metric. Next, the NHSN BSI measure should be used as it is superior to any claims based measure using V8 and V9 modifier code. . Lastly, and most importantly, the NQF needs to reconvene its expert committee to endorse the submitted phosphorous measure. With the inclusion of oral drugs in the bundled payment system in 2014, there is now question that CMS will be forced to implement such a measure. That measure will be implemented with or without NQF endorsement, but we urge the NQF to consider this inevitability in its deliberations and approve the current measure.

We are supportive of the processes that lead to the development of these measures with one notable exception. Measures need to be subjected to data feasibility BEFORE submission the NQF. Without this needed step, the NQF will receive a large number of measures unsuitable for use as was the case in this cycle of measure development and review. CMS and NQF need to work collaboratively to ensure that this does not happen again.

Sincerely,



Allen R. Nissenson, M.D.
Chief Medical Officer - OCMO



April 21, 2011

National Quality Forum
601 Thirteenth Street, NW
Suite 500 North
Washington, DC 20005

Subject: End Stage Renal Disease 2010 Project, 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 End Stage Renal Disease (ESRD) 2010: A Consensus Report*. Kidney Care Partners (KCP) is an alliance of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care – patient advocates, dialysis 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 ESRD. We greatly appreciate NQF undertaking this important work and commend the significant contributions of the Steering Committee and NQF staff.

The NQF report recommends 11 measures 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.

II. Measures Recommended by NQF

NQF recommends 11 measures, 10 of which KCP generally supported, some with caveats.

- a. **NQF 1454 Upper Limit for Total Uncorrected Serum Calcium (CMS):** Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

Comment: Mineral and Bone Disorder measures are specifically noted in MIPPA as an important area for quality measurement. KCP supports this measure for public reporting and payment. We also recommend that future development of measure for a lower limit for serum calcium be pursued.

- b. **NQF 1460 National Healthcare Safety Network (NHSN) Bloodstream Infection Measure (CDC):** Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient months.

Comment: KCP supports this measure for public reporting only.

- c. **NQF 1438 Periodic Assessment of Post-Dialysis Weight by Nephrologists (CMS):** Proportion of patients who have documentation of receiving a post-dialysis weight assessment from a nephrologist in the reporting month. (Recommended for time-limited endorsement)

Comment: KCP recognizes the important area this measure addresses, but does not support this measure at the facility level. KCP believes this aspect of care should be assessed at the clinician level. KCP also notes that the specifications require a “prescription,” and recommends this be modified to an “assessment,” as indicated in the description—a *new* prescription may not be necessary after the assessment. By “assessment,” we mean documentation in the medical record/CROWNWeb that the assessment was done and either a new prescription was written or one was not required. We also note that the denominator is specified as “Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD).” We note this measure is also appropriate for home hemodialysis and peritoneal dialysis patients.

- d. **NQF 1463 Standardized Hospitalization Ratio (SHR) for Admissions (CMS):** Risk-adjusted standardized hospitalization ratio for admissions. The measure is designed to reflect the number of hospitalization ‘events’ for the patients at a facility, relative to the number of hospitalization events that would be expected based on overall national rates and the characteristics of the patients at that facility.

Comment: KCP recognizes the important area this measure addresses and supports it for public reporting only, subject to certain modifications. As the measure is currently specified, it encompasses all admissions. KCP recommends the specifications be modified to “Risk-adjusted standardized hospitalization ratio *for dialysis access-related infections and fluid overload*,” with the numerator and denominator limited to the appropriate DRGs for dialysis access-related infections and fluid overload. In addition to this recommended change, we note that the measure developer, CMS, needs to provide greater transparency of methodology—in particular clarity with respect to the denominator of “expected” hospitalizations?

- e. **NQF 1418 Frequency of HD Adequacy Measurement for Pediatric Patients (CMS):** Percentage of all pediatric (<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.

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

- f. **NQF 1421 Method of HD Adequacy Measurement for Pediatric Patients (CMS):** Percentage of pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.

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

- g. **NQF 1423 Minimum spKt/V for Pediatric Hemodialysis Patients (CMS):** Percentage of all pediatric (<18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the reporting period.

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

- h. **NQF 1425 Measurement of nPCR for Pediatric HD Patients (CMS):** Percentage of pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements. (Recommended for time-limited endorsement)

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

- i. **NQF 1424 Monthly Hemoglobin Measurement for Pediatric Patients (CMS):** Percentage of all pediatric (<18 years old) hemodialysis patients and peritoneal dialysis patients who have monthly measures for hemoglobin. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

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

- j. **NQF 1430 Lower Limit of Hemoglobin for Pediatric Patients (CMS):** Percentage of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients, with ESRD ≥ 3 months, who have a mean hemoglobin <10 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

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

- k. **NQF 1433 Iron Therapy for Pediatric Patients (CMS):** Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin <11.0 g/dL and in whom simultaneous values of serum ferritin concentration was <100 ng/ml and TSAT <20% who received IV iron or were prescribed oral iron within the following three months. (Recommended for time-limited endorsement)

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

III. Measures Not Recommended by NQF

In addition to the measures just noted, KCP offers the following comments on two measures not recommended and strongly encourages their reconsideration. Specifically, we recommend that these measures be advanced for voting as voluntary consensus standards.

- l. **NQF 1427 Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl (Genzyme):** Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.

Comment: KCP supports this measure for public reporting and payment, and we recommend this measure be advanced to the voting phase. We believe high serum phosphorus is a biomarker that is important to monitor. In addition, with the implementation of the bundled payment system (in particular the forthcoming inclusion of oral medications in the bundle), measures that can assess appropriate treatment/undertreatment are central to evaluate quality of care for ESRD patients.

- m. **NQF1429 Avoidance of Iron Therapy in Iron Overload (CMS):** Percentage of all adult (≥ 18 years old) dialysis patients with a serum ferritin ≥ 1200 ng/mL or a TSAT $\geq 50\%$ on at least one measurement during the three-month study period who did not receive IV iron in the following three months.

Comment: KCP supports this measure for public reporting only, and we recommend this measure be advanced to the voting phase. Again, given implementation of the bundled payment system, we believe this is an appropriate measure to evaluate quality of care for ESRD patients.

IV. 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 (lmcgon@msn.com or 203.298.0567) if you have any questions.

Sincerely,

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

April 20, 2011

Helen Burstin, MD, MPH
Senior Vice President, Performance Measures
National Quality Forum
601 13th Street NW, Suite 500 North
Washington, DC 20005

RE: Comment on National Voluntary Consensus Standards for End-Stage Renal Disease

Dear Dr. Burstin,

On behalf of sanofi-aventis, we are pleased to respond to National Quality Forum's (NQF) call for comments on the project: National Voluntary Consensus Standards for End-Stage Renal Disease (ESRD). We acknowledge the impact of ESRD on patients and families as well as the overall burden on society. We therefore support efforts by NQF in the use of consensus standards to drive significant improvements in the care received by pediatric and adult patients with ESRD. In particular, sanofi-aventis recognizes the need to increase the number of standards focusing on the pediatric population, a theme which is reflected in the choice of seven of the eleven proposed quality measures recommended by the steering committee. Overall, sanofi-aventis applauds continuing efforts by NQF to influence the quality of care for patients with ESRD and we look forward to being fully engaged with the upcoming endorsement maintenance cycle project for renal disease.

Although NQF has already endorsed 25 measures through its 2008 National Voluntary Consensus Standards for ESRD project, we believe significant gaps remain, specifically with respect to iron deficiency anemia and the use of iron therapy. Therefore we, take this opportunity to highlight the need for further research into the treatment of iron deficiency anemia in ESRD patients undergoing hemodialysis. For example, with regards to a measure that was not recommended for endorsement namely, 'Avoidance of Iron Therapy in Iron Overload' (1429), a reason given by the committee for not recommending the measure was that definitions of iron overload are not evidence-based. While the measure developer selected 1200 ng/ml as the threshold above which iron should not be administered, there is little published evidence to support this threshold. This calls for broader research into appropriate markers for determining the adequacy of iron therapy in the context of overall clinical benefit and safety.

In addition, from the DRIVE study there is evidence to support clinical benefits and safety of intravenous (IV) iron therapy in anemic hemodialysis patients with serum ferritin between 500 ng/ml and 1200 ng/ml and transferrin saturation (TSAT) below <25%¹. As an extension of DRIVE, the DRIVE-II study found that epoetin requirements were reduced in patients who received iron during DRIVE while they remained the same for the control (no iron therapy) group². The outcome of DRIVE-II has significant implications because lower utilization of epoetin is associated with a lower risk of

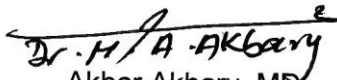
¹ Coyne DW, Kapoian T, Suki W, et al. Ferric gluconate is highly efficacious in anemic hemodialysis patients with high serum ferritin and low transferrin saturation: results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) Study. J Am Soc Nephrol 2007; 18:975

² Kapoian T, O'Mara NB, Singh AK, et al. Ferric gluconate reduces epoetin requirements in hemodialysis patients with elevated ferritin. J Am Soc Nephrol. 2008;19:372-379

adverse events such as strokes and cardiovascular events^{3,4}. However, current National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines specify a serum ferritin of 500 ng/ml as the threshold above which iron therapy decisions should be made after evaluating the patient's clinical status and the results of additional tests such as TSAT and hemoglobin⁵. Given that clinical guidelines have significant influence on clinical practice and when tied to incentives have the potential to change patient outcomes, this highlights the need for further research into the clinical benefits of wider adoption of this alternative treatment strategy, i.e., treating up to 1200 ng/ml.

In conclusion, sanofi-aventis fully supports this project and looks forward to seeing the development, endorsement, and use of additional performance measures in the ESRD space as tools to promote improvements in patient-centered care.

Sincerely,


Akbar Akbar, MD
Senior Director
US Medical Affairs

³ Phrommintikul A, Haas SJ, Elvik M, Klum H: Mortality and target haemoglobin concentrations in anemia patients with chronic kidney disease treated with erythropoietin: A meta-analysis. Lancet 369: 381–388, 2007.

⁴ Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M, Reddan, CHOIR Investigators: Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 355: 2085–2098, 2006.

⁵ K/DOQI Clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease. Am J Kidney Dis 2006; 47(Suppl 3):S1.



April 21, 2011

National Quality Forum
601 Thirteenth Street, NW
Suite 500 North
Washington, DC 20005

Subject: End Stage Renal Disease 2010 Project, 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 End Stage Renal Disease (ESRD) 2010: A Consensus Report*. Kidney Care Partners (KCP) is an alliance of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care – patient advocates, dialysis 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 ESRD. We greatly appreciate NQF undertaking this important work and commend the significant contributions of the Steering Committee and NQF staff.

The NQF report recommends 11 measures 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.

II. Measures Recommended by NQF

NQF recommends 11 measures, 10 of which KCP generally supported, some with caveats.

- a. **NQF 1454 Upper Limit for Total Uncorrected Serum Calcium (CMS):** Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL.

Comment: Mineral and Bone Disorder measures are specifically noted in MIPPA as an important area for quality measurement. KCP supports this measure for public reporting and payment. We also recommend that future development of measure for a lower limit for serum calcium be pursued.

- b. **NQF 1460 National Healthcare Safety Network (NHSN) Bloodstream Infection Measure (CDC):** Number of hemodialysis outpatients with positive blood cultures per 100 hemodialysis patient months.

Comment: KCP supports this measure for public reporting only.

- c. **NQF 1438 Periodic Assessment of Post-Dialysis Weight by Nephrologists (CMS):** Proportion of patients who have documentation of receiving a post-dialysis weight assessment from a nephrologist in the reporting month. (Recommended for time-limited endorsement)

Comment: KCP recognizes the important area this measure addresses, but does not support this measure at the facility level. KCP believes this aspect of care should be assessed at the clinician level. KCP also notes that the specifications require a “prescription,” and recommends this be modified to an “assessment,” as indicated in the description—a *new* prescription may not be necessary after the assessment. By “assessment,” we mean documentation in the medical record/CROWNWeb that the assessment was done and either a new prescription was written or one was not required. We also note that the denominator is specified as “Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD).” We note this measure is also appropriate for home hemodialysis and peritoneal dialysis patients.

- d. **NQF 1463 Standardized Hospitalization Ratio (SHR) for Admissions (CMS):** Risk-adjusted standardized hospitalization ratio for admissions. The measure is designed to reflect the number of hospitalization ‘events’ for the patients at a facility, relative to the number of hospitalization events that would be expected based on overall national rates and the characteristics of the patients at that facility.

Comment: KCP recognizes the important area this measure addresses and supports it for public reporting only, subject to certain modifications. As the measure is currently specified, it encompasses all admissions. KCP recommends the specifications be modified to “Risk-adjusted standardized hospitalization ratio *for dialysis access-related infections and fluid overload*,” with the numerator and denominator limited to the appropriate DRGs for dialysis access-related infections and fluid overload. In addition to this recommended change, we note that the measure developer, CMS, needs to provide greater transparency of methodology—in particular clarity with respect to the denominator of “expected” hospitalizations?

- e. **NQF 1418 Frequency of HD Adequacy Measurement for Pediatric Patients (CMS):** Percentage of all pediatric (<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.

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

- f. **NQF 1421 Method of HD Adequacy Measurement for Pediatric Patients (CMS):** Percentage of pediatric (<18 years old) in-center HD patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.

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

- g. **NQF 1423 Minimum spKt/V for Pediatric Hemodialysis Patients (CMS):** Percentage of all pediatric (<18 years old) in-center HD patients who have been on hemodialysis for 90 days or more and dialyzing 3 or 4 times weekly whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the reporting period.

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

- h. **NQF 1425 Measurement of nPCR for Pediatric HD Patients (CMS):** Percentage of pediatric (<18 years) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements. (Recommended for time-limited endorsement)

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

- i. **NQF 1424 Monthly Hemoglobin Measurement for Pediatric Patients (CMS):** Percentage of all pediatric (<18 years old) hemodialysis patients and peritoneal dialysis patients who have monthly measures for hemoglobin. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

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

- j. **NQF 1430 Lower Limit of Hemoglobin for Pediatric Patients (CMS):** Percentage of pediatric (<18 years old) hemodialysis and peritoneal dialysis patients, with ESRD ≥ 3 months, who have a mean hemoglobin <10 g/dL for a 3 month reporting period, irrespective of ESA use. The hemoglobin value reported at the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

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

- k. **NQF 1433 Iron Therapy for Pediatric Patients (CMS):** Percentage of all pediatric (<18 years old) hemodialysis and peritoneal dialysis patients with hemoglobin <11.0 g/dL and in whom simultaneous values of serum ferritin concentration was <100 ng/ml and TSAT <20% who received IV iron or were prescribed oral iron within the following three months. (Recommended for time-limited endorsement)

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

III. Measures Not Recommended by NQF

In addition to the measures just noted, KCP offers the following comments on two measures not recommended and strongly encourages their reconsideration. Specifically, we recommend that these measures be advanced for voting as voluntary consensus standards.

- l. **NQF 1427 Adult Dialysis Patients - Serum Phosphorus Greater Than 6 mg/dl (Genzyme):** Proportion of patients with 3-month rolling average of serum phosphorus greater than 6 mg/dL.

Comment: KCP supports this measure for public reporting and payment, and we recommend this measure be advanced to the voting phase. We believe high serum phosphorus is a biomarker that is important to monitor. In addition, with the implementation of the bundled payment system (in particular the forthcoming inclusion of oral medications in the bundle), measures that can assess appropriate treatment/undertreatment are central to evaluate quality of care for ESRD patients.

- m. **NQF1429 Avoidance of Iron Therapy in Iron Overload (CMS):** Percentage of all adult (≥ 18 years old) dialysis patients with a serum ferritin ≥ 1200 ng/mL or a TSAT $\geq 50\%$ on at least one measurement during the three-month study period who did not receive IV iron in the following three months.

Comment: KCP supports this measure for public reporting only, and we recommend this measure be advanced to the voting phase. Again, given implementation of the bundled payment system, we believe this is an appropriate measure to evaluate quality of care for ESRD patients.

IV. 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 (lmcgon@msn.com or 203.298.0567) if you have any questions.

Sincerely,

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

April 20, 2011

Helen Burstin, MD, MPH
Senior Vice President, Performance Measures
National Quality Forum
601 13th Street NW, Suite 500 North
Washington, DC 20005

RE: Comment on National Voluntary Consensus Standards for End-Stage Renal Disease

Dear Dr. Burstin,

On behalf of sanofi-aventis, we are pleased to respond to National Quality Forum's (NQF) call for comments on the project: National Voluntary Consensus Standards for End-Stage Renal Disease (ESRD). We acknowledge the impact of ESRD on patients and families as well as the overall burden on society. We therefore support efforts by NQF in the use of consensus standards to drive significant improvements in the care received by pediatric and adult patients with ESRD. In particular, sanofi-aventis recognizes the need to increase the number of standards focusing on the pediatric population, a theme which is reflected in the choice of seven of the eleven proposed quality measures recommended by the steering committee. Overall, sanofi-aventis applauds continuing efforts by NQF to influence the quality of care for patients with ESRD and we look forward to being fully engaged with the upcoming endorsement maintenance cycle project for renal disease.

Although NQF has already endorsed 25 measures through its 2008 National Voluntary Consensus Standards for ESRD project, we believe significant gaps remain, specifically with respect to iron deficiency anemia and the use of iron therapy. Therefore we, take this opportunity to highlight the need for further research into the treatment of iron deficiency anemia in ESRD patients undergoing hemodialysis. For example, with regards to a measure that was not recommended for endorsement namely, 'Avoidance of Iron Therapy in Iron Overload' (1429), a reason given by the committee for not recommending the measure was that definitions of iron overload are not evidence-based. While the measure developer selected 1200 ng/ml as the threshold above which iron should not be administered, there is little published evidence to support this threshold. This calls for broader research into appropriate markers for determining the adequacy of iron therapy in the context of overall clinical benefit and safety.

In addition, from the DRIVE study there is evidence to support clinical benefits and safety of intravenous (IV) iron therapy in anemic hemodialysis patients with serum ferritin between 500 ng/ml and 1200 ng/ml and transferrin saturation (TSAT) below <25%¹. As an extension of DRIVE, the DRIVE-II study found that epoetin requirements were reduced in patients who received iron during DRIVE while they remained the same for the control (no iron therapy) group². The outcome of DRIVE-II has significant implications because lower utilization of epoetin is associated with a lower risk of

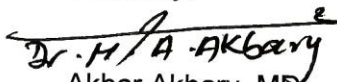
¹ Coyne DW, Kapoian T, Suki W, et al. Ferric gluconate is highly efficacious in anemic hemodialysis patients with high serum ferritin and low transferrin saturation: results of the Dialysis Patients' Response to IV Iron with Elevated Ferritin (DRIVE) Study. J Am Soc Nephrol 2007; 18:975

² Kapoian T, O'Mara NB, Singh AK, et al. Ferric gluconate reduces epoetin requirements in hemodialysis patients with elevated ferritin. J Am Soc Nephrol. 2008;19:372-379

adverse events such as strokes and cardiovascular events^{3,4}. However, current National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines specify a serum ferritin of 500 ng/ml as the threshold above which iron therapy decisions should be made after evaluating the patient's clinical status and the results of additional tests such as TSAT and hemoglobin⁵. Given that clinical guidelines have significant influence on clinical practice and when tied to incentives have the potential to change patient outcomes, this highlights the need for further research into the clinical benefits of wider adoption of this alternative treatment strategy, i.e., treating up to 1200 ng/ml.

In conclusion, sanofi-aventis fully supports this project and looks forward to seeing the development, endorsement, and use of additional performance measures in the ESRD space as tools to promote improvements in patient-centered care.

Sincerely,


Akbar Akbar, MD
Senior Director
US Medical Affairs

³ Phrommintikul A, Haas SJ, Elvik M, Klum H: Mortality and target haemoglobin concentrations in anemia patients with chronic kidney disease treated with erythropoietin: A meta-analysis. Lancet 369: 381–388, 2007.

⁴ Singh AK, Szczech L, Tang KL, Barnhart H, Sapp S, Wolfson M, Reddan, CHOIR Investigators: Correction of anemia with epoetin alfa in chronic kidney disease. N Engl J Med 355: 2085–2098, 2006.

⁵ K/DOQI Clinical practice guidelines and clinical practice recommendations for anemia in chronic kidney disease. Am J Kidney Dis 2006; 47(Suppl 3):S1.