OCMO
Relentless pursuit of quality

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

601 Hawaii Street El Segundo, CA 90245 | 1-800-313-4872 | www.davita.com/physicians

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.

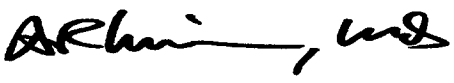
Conclusion

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