TO: NQF Members

FR: NQF Staff

RE: Voting Draft Report: *NQF-Endorsed Measures for Renal*

DA: August 19, 2015

Background

Renal disease is a leading cause of morbidity and mortality in the United States. More than twenty million adults (10% of the population) in the United States have chronic kidney disease (CKD). Untreated CKD can result in End Stage Renal Disease (ESRD) and a host of other health complications. Currently, over half a million people in the United States have received a diagnosis of ESRD, the only chronic disease covered by Medicare for people under the age of 65. Considering the high mortality rates and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

On May 6-7, 2015, NQF convened a new multi-stakeholder Standing Committee composed of 23 individuals to evaluate 14 NQF-endorsed maintenance measures and 11 new measures and make recommendations for endorsement. Thirteen measures were recommended for endorsement, three measures were recommended for endorsement with reserve status, the Committee did not recommend seven measures and did not reach consensus on two measures.

Comments Received

NQF solicits comments on measures undergoing review in various ways and at various times throughout the evaluation process. First, NQF solicits comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). Second, NQF solicits member and public comments prior to the evaluation of the measures via an online tool located on the project webpage. Third, NQF opens a 30-day comment period to both members and the public after measures have been evaluated by the full Committee and once a report of the proceedings has been drafted.

Pre-evaluation comments

The pre-evaluation comment period was open from March 23 to April 10, 2015 for 18 of the 25 measures under review. Comments on four dialysis measures stewarded by the Renal Physicians Association, the target weight measure stewarded by the Kidney Care Quality Alliance, the bloodstream infection measure stewarded by the Centers for Disease Control and Prevention and the optimal starts measure stewarded by Kaiser were not requested because measure submission materials could not be posted during this period. A total of 52 pre-evaluation comments were received on the remaining measures.

Post-evaluation comments

The Draft Report went out for Public and Member comment June 12 through July 13, 2015. During this commenting period, NQF received 97 comments from four member organizations:

Consumers – 0	Professional – 2
Purchasers – 0	Health Plans – 1
Providers – 0	QMRI – 1

Supplier and Industry – 0 Public & Community Health - 0

A complete table of comments submitted pre- and post-evaluation, along with the responses to each comment and the actions taken by the Standing Committee, is posted to the project page on the NQF website, along with the measure submission forms.

The Committee reviewed all comments received and considered the pre-meeting comments prior to making an endorsement recommendation. The Committee also responded to all post-evaluation comments. Revisions to the draft report and the accompanying measure specifications are identified as red-lined changes. (Note: Typographical errors and grammatical changes have not been red-lined, to assist in reading.)

Comments and their Disposition

Two major themes were identified in the post-evaluation comments, as follows:

1. Removal of Upper Boundary and Clarification of Frequency Requirements
2. Dialysis Access Considerations

Theme 1 - Removal of Upper Boundary and Clarification of Frequency Requirements

During the in-person meeting, Committee members supported endorsement of the following measures [#0249 (Delivered Dose of Hemodialysis Above Minimum), #0318 (Delivered Dose of Peritoneal Dialysis Above Minimum), and # 2704 (Minimum Delivered Peritoneal Dialysis Dose)], on the following conditions:

- The upper spKt/V requirement be removed; and
- The frequency of dialysis visits be clarified and consistent across measures: lowered from four visits a week to three visits or greater a week in order for patients to be included in the denominator.

Comments received supported the stipulations made to revise the measures and thus support the Committee's recommendations.

> **Developer Response:** Based on the discussion that took place at the NQF Standing Committee meeting, CMS has made the following revisions to the measure submission:
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> - The upper threshold for spKt/V values has been removed from the specifications
> - The specifications were edited to provide more clear descriptions of the numerator, denominator, exclusions, and calculation algorithm. These calculation clarifications are not material changes with respect to the documentation that the committee reviewed in May.
> - The evidence form was revised to include the abstracts for the pieces of evidence listed in 1a.8.2.
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> **Committee Response:** Requested changes have been made and the Standing Committee stands by its original recommendation.

Theme 2 - Dialysis Access Considerations

A number of measures in the Renal Portfolio focus on either minimizing use of catheters as a dialysis access strategy, or increasing the utilization of AV Fistulas or Grafts. Consistent with the Committee

discussions, commenters continued to encourage measure developers and stewards to consider patient characteristics when determining appropriateness of dialysis access type. Specifically, concerns were raised around the premise that catheters are clinically appropriate in some populations, and there may be the opportunity to exclude patients in hospice or with short life expectancy from receiving an AVF.

> **Developer Response:** Ongoing measure development includes the consideration of refinements to this measure that may mitigate the unintended consequences regarding special populations with limited life expectancy. The current NQF-endorsed vascular access quality measures supported by CMS are linked measures, incentivizing AV fistula use as a positive outcome and prolonged use of tunneled catheter as a negative outcome. These linked measures incorporate the clinical equipoise regarding these access types, effectively creating three categories of outcomes (AV fistula=positive; AV graft= neutral; prolonged use of tunneled catheter= negative).
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> **Committee Response:** Improving quality measures to accurately identify the clinically appropriate populations for inclusion and exclusion is evolving. There was significant discussion about potential measure revisions from a recently convened vascular access technical panel, which may further clarify these efforts. The Committee was charged with evaluating the measures as submitted and, while measure revisions may be forthcoming based on the Technical Expert Panel recommendations, the NQF criteria are met with the information provided.

Measure Specific Comments

2594: Optimal End Stage Renal Disease Starts (Kaiser)

One commenter supported the measure for endorsement and one did not. Three commenters supported the concept of the measure but had concerns with the construction of the measure. They expressed the measure was only feasible in fully integrated delivery care systems or large physician groups and could not be applied to dialysis facilities, or even ESRD Seamless Care Organizations (ESCOs), because neither includes CKD patients. Commenters suggested exclusions that address scenarios in which a permanent access may not be appropriately identified and also listed potential unintended consequences of implementing this measure.

> **Developer Response:** The Permanente Federation, measure developer for NQF Measure 2594, Optimal ESRD Starts, appreciates the comments submitted by both KCP and RPA and welcomes the opportunity to respond. It is critical that this important new measure be evaluated by the broader renal community and that a dialogue be established. Because there are several overlapping topics, we will respond to both comments simultaneously.
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> We share with KCP and RPA a desire to focus on patients and their needs as they deal with the complexities of chronic kidney disease. Taking a step back, the overarching need for patients who are approaching ESRD is for the health care system to identify them, educate them, and prepare them for ESRD. As we all appreciate, there is currently little focus on this process as the needed activities are generally not compensated for by CMS and commercial insurance. The goal of achieving NQF endorsement for this measure is to bring this deficit to the attention of health care payers so that they will reach out to these patients and avoid disastrous and costly unplanned onset of ESRD with a hemodialysis catheter in a central vein.

The double emphasis of Optimal ESRD Starts is for patients to have a planned ESRD start and to avoid the risks associated with a central venous hemodialysis catheter, particularly BSI and early mortality.

Intended level of analysis (health care entities appropriate to measure): Due to the check box nature of the online application process, it is difficult to describe on the application how this measure can best be used to improve outcomes for patients who are approaching ESRD. As pointed out by both KCP and RPA and also as stated several times in the application, the use is neither appropriate nor intended for dialysis providers who generally do not see patients before ESRD and have little or no opportunity to educate and coordinate care before ESRD. The entities that can impact Optimal ESRD Starts are CMS, commercial health plans, integrated care systems with CKD patients (not ESCOs) and large nephrology practices/nephrology associations with more than 50 new ESRD patients per year.

Patients not previously managed by nephrologists: The 40% of patients not assigned to a nephrologist until they start dialysis, as noted by KCP and RPA, are the exact patients this measure can help address when applied at the payer level. In America today, with the presence of electronic laboratory data, every patient with advanced chronic kidney disease can be identified, and then educated about dialysis modalities and kidney transplantation, referred to a nephrologist and be prepared before ESRD. In most cases, the abnormal labs (creatinine, urine protein) were paid for by CMS or a health insurance plan and it is in their best interest and is their responsibility to reach out to these patients and bring them into a process leading to an Optimal ESRD Start.

At the nephrologist level, patients who reach ESRD without seeing a nephrologist may not be attributed to the nephrologist who takes on their care. Pre-ESRD patients under the management of a nephrologist and team however, share the responsibility to help patients have an Optimal ESRD Start. And when sufficient numbers of new ESRD patients can be grouped together (50 or more per year), the performance of the nephrologist and their teams may be measured.

Additional exclusions: Before discussing individual proposed denominator exclusions, we would like to point out that the Optimal ESRD Starts target could never be 100% for a number of reasons, but that the 2012 35.5% US outcome is far below what can be accomplished. The goal is to have systems in place to identify and support the majority of patients approaching ESRD, and we must keep an eye to the larger mission. Furthermore, every exclusion means more data elements must be collected, as well as tested for reliability and validity.

The third exclusion suggested by both KCP and RPA is actually in place, not as an exclusion but defined in the denominator statement: “The population being measured are patients age 18 and over who 1) receive a preemptive kidney transplant (having never received outpatient dialysis), including simultaneous pancreas and kidney transplant, plus 2) patients age 18 and over initiating long-term maintenance dialysis who do not recover kidney function by 90 days.” This is 90 days as opposed to the suggested 4 months. Of course the longer the waiting time, the more

patients will recover GFR and be able to stop dialysis. However, the calculation of the metric already requires a 90 day waiting period for acute renal failure recovery, and there needs to be a compromise to keep the results more current and meaningful. Since the vast majority of patients who will recover have recovered by 90 days, we feel that is an adequate time period.

The first two proposed exclusions from both the KCP and the RPA involve decisions for the frail elderly which is an area of much interest in the renal literature in the last couple years. We agree that Fistula First is not the correct approach for all patients and that the frail elderly probably do need a different pathway to ESRD, including the option to not start dialysis (such patients are not in the denominator), and the use of grafts or even catheters for a trial or for a planned short duration of dialysis. At this time the medical evidence is not clear about an ideal pathway for such patients. Within KP, we are discussing alternative programs for the frail elderly. We expect that if this measure is endorsed, by the time this measure is up for re-endorsement in 3 years there may be sufficient medical evidence and global agreement to provide an exclusion for these patients. We would be happy to work with your organizations on this.

In the area of unintended consequences, we agree that these specific situations bear close monitoring. 1) In the case of promoting urgent start PD, we view this as a very good thing and it is included in the numerator definition. We believe in Home Dialysis first unless patients clearly are incapable. It is difficult to imagine urgent start PD being inappropriately used in an unqualified candidate in order to game the system. But even if such a patient quickly failed PD, there is no penalty in the measure for switching to in-center hemodialysis later. 2) Single needle in fistula with second line in catheter – our view is that this is not optimal, exposes the patient to catheter sepsis and is a failure of the system to prepare the patient. We recognize that sometimes the fistula is not quite ready when the patient has to start hemodialysis and recognize that the perfect algorithm for fistula placement may never be discovered. This is one reason why the measure's target will never be 100%, but such failures should be looked at as opportunities to improve the system for future patients. 3) Low socioeconomic status: All patients deserve the chance for an Optimal ESRD Start, regardless of their socioeconomic status. We recognize the reality of current disparities in care but hope that if they do exist in this process and are brought into the light, that there will be an opportunity for better outcomes in the future.

Committee Response: Requested changes have been made and the Standing Committee stands by its original recommendation.

NQF Member Voting

Information for electronic voting has been sent to NQF Member organization primary contacts. Accompanying comments must be submitted via the online voting tool.

Please note that voting concludes on September 2, 2015 at 6:00 pm ET – no exceptions.