

On Monday, March 31, 2014, the Centers for Medicare and Medicaid Innovation (CMMI) contractor IMPAQ requested public comment on its Technical Expert Panel's (TEP) recommendation for quality measures to assess the ESRD Seamless Care Organizations (ESCO) program. IMPAQ's method of collecting comments was via an online survey tool, as opposed to a traditional comment letter, and as such, only gave the commenters the options of "support"; "oppose"; or "support with changes." The below ASN comments represent the submitted response to the proposed measures via the survey tool.

Overarching comments:

In any capitated model, the key elements to capture in metrics are minimum thresholds to ensure that a basic standard of care is delivered. Second, optimizing patient quality of life and/or satisfaction and/or other patient-reported outcomes are important. Third, if the care organization is targeting a very specific population, metrics should be as specific as possible to that population. Fourth, ESCOs are incentivized to reduce expensive hospital-based care; this means that metrics designed to reduce hospitalizations and other expensive care may, in fact, be redundant and thereby may result in greater administrative demands with no tangible effect on clinical outcomes. For example, all ESCOs that exhibit foresight will have protocols for foot exams and medication reconciliation as these will be cost saving measures. Accordingly, is a metric which will increase administrative demands without any improvement in actual processes necessary? Fifth, case mix adjustment methodology remains undescribed. Finally, it is unclear how these metrics will interface with existing metrics in the QIP as well as interpretative guidance in the Conditions for Coverage, although it is stated that the QIP metrics will be applied to the ESCO model. Critically, when QIP measures overlap with or supersede an ESCO measure, how will this be addressed?

We acknowledge that the ESCOs, at least initially, are a pilot project, and recognize that flexibility and a willingness for both providers and policymakers to adapt to circumstances will be essential for this program to succeed. We have no expectation that metrics in this system will be perfect from the outset, but we do expect that the community and CMS will be able to work together to improve these metrics going forward. It is within this framework that we comment on the items below.

- **Kidney Disease Quality of Life Instrument (KDQOL)—Support with Changes**
 - a. ASN understands the need for quality of life/ satisfaction indicator, but it is unclear on how this measure will be implemented. Is it a process measure? Is there a numerator? We agree that a measure of quality of life should be included in a fully capitated system but require more details to offer an educated comment.
- **NQF #0055: Diabetes Care: Eye Exam—Support with Changes**
 - a. ASN supports this measure in concept, but believes that CMS needs to define the patients that are mandated to take this eye exam. For example, patients who are legally blind due to complications with diabetes should not be mandated or have to be subjected to this test. This is an example where the metric needs to be tailored to the population, recalling that half of all dialysis patients have diabetes severe enough to significantly damage one organ (the kidney) and therefore already have substantial disease in other organs (for example, the eyes).
- **NQF #0056: Diabetes: Foot exam —Support with Changes**

- a. ASN supports this measure and believes it can have a substantial effect on patient health and overall care; however, we note that the ESCO structure already incentivizes doing diabetes foot examinations and that documenting this for administrative purposes may not be an efficient use of resources. Accordingly, if included, we call upon CMS to reconsider this measure in the future if it is demonstrated that there is no achievement gap. With regard to the specific measure, patients 75 years-old and older are excluded. ASN believes this measure should include patients over the age of 75 considering the patient population of most dialysis facilities. Also, the measure does not distinguish who is doing this observation, and how often. We believe this should be administrated by a range of healthcare providers, including RN's and PA's. Finally, although unfortunate, there are a substantial number of double amputees in the dialysis population, reflecting that diabetes severe enough to significantly damage the kidneys often has major effects on the vasculature and/or have severe neuropathy. The current exclusion is that they had amputations performed during the measurement period, but many patients have pre-existing amputations. These question need to be answered before this measure is included.
- NQF #0089: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care—**Do not Support**
 - a. ASN is unclear on how this measure would not apply to the ESCO program, particularly given the incorporation of NQF #0055 and the likelihood that dialysis physicians will be managing many aspects of diabetes care within an ESCO.
 - (PQI 16) Rate of Lower Extremity Amputation Among Patients with Diabetes—**Support With Changes**
 - a. ASN supports a measure addressing this topic, but, as written, the metric itself is not appropriate for ESRD but rather is directed to larger populations. Specifically, this is an area-level indicator that is not designed to apply to an ESCO population likely ranging from 350-1000 beneficiaries.
 - NQF #0070: Chronic stable coronary artery disease: blocker therapy—prior myocardial infarction (MI) or left ventricular systolic dysfunction (LVEF <40%) (PCPI)—**Do not Support**
 - a. ASN does not support this measure, and believes there is no high-level evidence for patients undergoing maintenance dialysis to justify this measure. There are no data for the efficacy of beta-blocker therapy in dialysis patients following MI (and, the metric refers to discharge beta-blocker use for MI). The only current data in dialysis supporting beta-blocker use in heart failure is from a 2003 Italian study in only 114 patients using carvedilol for dilated cardiomyopathy (Cice et al, J Am Coll Cardiol 2003). This does not meet data standards for a population specific metric. Critically, in dialysis, it is important to remove sufficient fluid with each treatment to achieve a certain “dry weight” that likely represents euvolemia; use of a beta-blocker with its associated antihypertensive effects may adversely impact achievement of this goal and cause more harm than good, at least in some patients. Accordingly, at this time, ASN does not support this measure and believes that it is not a good metric for the ESRD population.

- NQF #0081: Heart failure: ACE inhibitor or ARB therapy for left ventricular systolic dysfunction (PCPI) —**Do not Support**
 - a. ASN does not support this measure and believes that there are not sufficient data to justify this measure. While there are many dialysis patients with low ejection fraction who may potentially benefit from ACEi or ARB therapy, others have chronic hypotension and often cannot tolerate these agents without increasing the likelihood of volume overload. Furthermore, dialysis patients are at higher risk for hyperkalemia further raising safety concerns with this class of medications. Clinically, most nephrologists feel it is more important to be able to achieve volume control, managing afterload in that manner, than use specific medications. This is an area that requires an adequately powered clinical trial before being incorporated into a metric.

- NQF #0369: Dialysis Facility Risk-Adjusted Standardized Mortality Ratio —**Support with Changes**
 - a. ASN supports this metric, with the caveats that we have previously raised regarding the ability to adequately case mix adjust and account for planned dialysis withdrawals.

- NQF #41: Influenza Immunization —**Support with Changes**
 - a. ASN supports this measure and believes that immunizations of this nature should be given to patients of all ages; accordingly, we suggest extending this measure to all dialysis patients.

- NQF #43: Pneumococcal Vaccination —**Support with Changes**
 - a. ASN supports this measure and believes that immunizations of this nature should be given to patients of all ages; accordingly, we suggest extending this measure to all dialysis patients.

- NQF #418: Depression Screening —**Support with Changes**
 - a. ASN believes that a depression/mental health measure is crucial for patient satisfaction and overall health, and we support screening for depression as well as development of a treatment plan for depression. We note that this measure, as written, is not geared for the ESRD population and therefore cannot support this measure as written here, but we do support a similar metric that is geared to the dialysis population.

- NQF #0028: Tobacco Use: Screening and Cessation Intervention
 - a. ASN supports this metric for dialysis application.

- TBD: Standardized Readmission Ratio (SRR) for Dialysis Facilities —**Support with Changes**
 - a. ASN supports this measure in concept, although recognizes that substantial work is needed to clarify this measure. Case mix adjustment remains uncertain as does coping with incident dialysis patients. That said, the SRR is less subject to biases from case mix than the SHR. Additionally, unlike the SRR metric suggested for the QIP, the ESCO is incentivized to have a presence in hospitals, and therefore the issue of the dialysis facility having opportunity to intercede

before the patient reaches the dialysis facility is less of an issue for an ESCO. Finally, ASN believes that admissions to PPS-exempt cancer hospitals should not be excluded from the ESCO measure as the measure reflects ESCO care rather than cancer hospital care and this system could theoretically result in ESCOs preferentially partnering with PPS-cancer exempt hospitals in cities where there is a choice between a PPS-exempt cancer hospital and a cancer center that is not PPS-exempt. This clause seems counter to the spirit of the ESCO system and fair marketplace competition.

- NQF #: 1463: Standardized Hospitalization Ratio for Admissions —**Support with Changes**
 - a. ASN supports this measure, however, believes that CMS does not need to have admission and readmissions measure; given data on the effects of reducing readmissions on reducing admissions, ASN would recommend that the readmission measure be refined and used rather than the SHR.

- NQF #0326: Advance Care Plan —**Support with Changes**
 - a. ASN supports this measure, but believes that this measure should encompass more than just patients 65 years and older.

- NQF #0419: Documentation of Current Medications in the Medical Record —**Support with Changes**
 - a. ASN supports medication reconciliation. We are uncertain as to the request to comment on NQF #0419 and NQF #0097. The concept within NQF #0419 seems more appropriate for the ESCO program, but remains unrefined for this purpose. Specific modifications are required for use in an ESCO.

- NQF #TBD: Functional Status Assessment for Complex Chronic Condition —**Do not Support**
 - a. ASN does not support this measure as all dialysis patients have a complex chronic condition – kidney failure is nearly as complex of a chronic condition as exists in medicine. We were unsure what heart failure had to do with this. The potential tools elected for this proposed metric (Veterans-RAND 12-Item Health Survey [VR-12]; Veterans-RAND 36-item Health Survey [VR-36]; Minnesota Living with Heart Failure Questionnaire [MLHF-Q]; Kansas City Cardiomyopathy Questionnaire [KCCQ]; PROMIS-10 Global Health, PROMIS-29) are not validated for use in the dialysis population and have tremendous overlap with the KDQOL. For many reasons, although an important topic, this metric should not be included.

- NQF #0059: Diabetes hemoglobin a1c poor control —**Do not Support**
 - a. ASN does not support this measure. The HbA1C is not a reliable test in dialysis patients, target HbA1C level remains unknown and ESCOs are already incentivized to reduce diabetes complications.

- NQF #0068 : Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic —**Do not Support**

- a. ASN does not support this metric based on the lack of data in dialysis patients.

- NQF #0083: **Heart Failure: Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) —Do not Support**
 - a. ASN does not support this measure, and believes there are no significant data in the area of dialysis to justify this measure. The only current data in dialysis supporting beta-blocker use in heart failure is from a 2003 Italian study in only 114 patients using carvedilol for dilated cardiomyopathy (Cice et al, J Am Coll Cardiol 2003). This does not meet data standards for a population specific metric. Critically, in dialysis, physicians typically prefer to get dry weight down to a desired target; use of a beta-blocker with its associated antihypertensive effects may adversely impact achievement of this goal and cause more harm than good, at least in some patients. Accordingly, at this time, ASN does not support this measure and believes that it is not a good metric for the ESRD population.

- NQF #1789: Hospital-Wide All-Cause Unplanned Readmission Measure (HWR) —**Do not Support**
 - a. ASN does not support this measure. It does not apply to dialysis patients and there is a different measure in this list that directly applies to dialysis patients. We do not understand this duplication and strongly urge that measures for an ESCO specifically be geared to dialysis populations.

- NQF 0097: Medication Reconciliation —**Support with Changes**
 - a. ASN supports medication reconciliation for dialysis patients. This metric refers to reconciliation within 60 days of discharge and does not seem to apply to the dialysis environment. Therefore ASN does not support this metric for adoption into the ESCO program

- NQF Pending: Standardized Transfusion Ratio —**Support with Changes**
 - a. ASN supports this metric in concept but requires more details of the final metric to offer a firm comment. One of the major issues with the QIP is the lack of an anemia floor measure, a shortcoming that is critical in a capitated system. We are uncertain as to the reason for exclusion of 'carcinoma in situ' and for 'solid organ tumors' if they are early stage and resected. These are minor comments.