KIDNEY CARE PARTNERS

March 31, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation & Quality
Chief Medical Officer
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244s

Dear Dr. Conway:

On behalf of Kidney Care Partners (KCP), I am writing to share our comments on the measures identified through the IMPAQ Technical Expert Panel (TEP) measure development process for the Comprehensive End Stage Renal Disease Care (CEC) Initiative (referred to collectively as the "CEC TEP "). While we have provided these comments to IMPAQ through the formal web-based submission process, we also wanted to share our comments with you, given that many of the concerns we have raised with regard to previous TEP processes remain unresolved. We also wanted to highlight our concerns with specific measures in light of your role in determining whether any of these measures will or will not be used within the various CMS programs, including the CEC Initiative.

KCP is an alliance of members[1] of the kidney care community that serves as a forum for patient advocates, dialysis care professionals, providers, and manufacturers to advance policies that support the provision of high quality care for individuals with both chronic kidney disease (CKD) and End-Stage Renal Disease (ESRD).

KCP continues to express concerns about the process used to identify, consider, and make recommendations about the measures. While KCP supports some of the measures proposed, we have highlighted those measures that are not yet appropriately defined to be included in the CEC Initiative.

I. CMS Should Reform the TEP Measure Development/Identification Process.

KCP continues to have concerns about the process used to identify the measures for which comment has been sought. While there have been some improvements in the process, many of the issues we have raised in the past remain unresolved. For example, there are ongoing problems with modifications being made to the specifications; yet, the measures are still being represented as having the endorsement of the National Quality Forum (NQF), when they do not. At best, the process creates significant confusion as to what is actually being considered, while at worst it appears that the TEP is viewed as a rubber stamp.

Maine1 *See* Appendix A for list of members.

As you know, KCP is deeply committed to developing ways to measure the quality of care provided in the Medicare ESRD program. As an organization and as individual member companies, we have invested significant resources to assist in the strategic planning, measure development, and measure implementation efforts. Our goal has always been to partner with CMS so that the measures developed (whether for reporting, the ESRD Quality Incentive Program (QIP), or coordinated care pilots, such as the CEC Initiative) are meaningful and accurate in reporting the care beneficiaries are receiving. Despite these efforts, the Agency has not established a transparent process that promotes confidence among beneficiaries, providers, and others in the kidney care community that the metrics are in fact focused on the right drivers of quality care or specified in a way that will accurately measure the care being provided.

We recognize that CMS has solicited input on the specific measures identified in the CEC TEP; however, we believe it is important for the Agency to understand why the community continues to view the process as flawed. Once again, we have outlined a set of recommendations that, if implemented, would increase the trust in the processes necessary to ensure community support of Medicare quality initiatives that rely on TEP developed/identified metrics. Specifically, we request that CMS:

- Improve the transparency of the TEP process by:
    - Sharing the agenda and other materials to interested stakeholders broadly through the CMS website or a related website prior to the TEP meeting and with sufficient time to consider it.
    - Providing for a more open process by allowing non-TEP members to listen in on the TEP work group calls and to provide comments at the end of these calls and/or in writing via email to the CMS staff member coordinating the particular group. These comments should be shared with the TEP members for their consideration as they develop the TEP recommendations.
    - Increasing transparency in the TEP grading criteria by having overt grading by each panel member and identification of these (or voting) results.
    - Publicly posting all comments it receives along with the response to each in a fashion similar to that deployed by CMS during rulemaking and NQF during its review of measures.
- Improve the substantive process within the TEPs by:
    - Providing TEP members with sufficient time to review the materials that will be the subject of the TEP discussions. These materials should be complete, organized, and accurate. For example, if measures specifications are not available, that "measure" should not be considered.
    - Instructing TEP members to evaluate measures not solely on their clinical significance, but also on the ability to implement them in the dialysis setting, their impact on morbidity and mortality (including improved health-related quality of life for patients), and their appropriateness for being reported and

and/or incorporated into the CMS quality initiatives.

KCP would welcome the opportunity to work more closely with the Agency to improve the TEP process.

II. While KCP Supports with Comment Some of the CEC TEP Measures, CMS Should Not Adopt Several of the Proposed Measures for the CEC Initiative.

As a threshold matter, KCP strongly objects to the pattern throughout the proposed measure set of providing an NQF number, from which one logically infers that the measure is NQF-endorsed, when in fact the specifications differ from those evaluated by NQF. We document throughout our comments where this has occurred. Specifications, in all their detail, define the measure. Thus, we emphasize in the strongest possible terms the absolutely critical importance of accurately characterizing a measure as NQF-endorsed. NQF endorsement means NQF has evaluated those specifications with an important degree of rigor, and NQF members have considered and approved them as voluntary consensus standards. Changes to specifications are a different measure, period. They may not materially impact a measure score when implemented, but that is unknown unless documented and validated. Presenting specifications as NQF-endorsed when, in fact differences are present, is inaccurate and disingenuous.

We note that if the measure is undergoing changes as part of a regular NQF maintenance process, then it is a straightforward matter to note that any changes present in the proposed measure reflect this via the use of redline. If such changes are not under review by NQF, characterizing a proposed measure as based on an NQF-endorsed measure and/or are e-specifications derived from an NQF-endorsed measure—and again identifying the differences through redline—is more accurate and transparent. Finally, we posit that if changes are made to a previously NQF-endorsed measure that CMS wishes to characterize as based on an existing measure, it is incumbent on CMS to justify the deviation and provide the necessary data upon which validity can be re-determined.

- **NQF 0056: Diabetes Care: Foot Exam.** KCP supports the directionality of this clinician-level measure. KCP is concerned, however, about the applicability of this measure only to patients aged 75 years and younger, since many dialysis patients fall outside this age range; we recommend patients aged 18 years and older as that would be more inclusive. KCP also notes that the measure is referred to as 0056, but the specifications presented differ from those currently under endorsement maintenance review by NQF. Specifically, NQF 0056 (version under review) excludes patients with steroid-induced diabetes, while the proposed CEC TEP measure does not; this discrepancy should be reconciled and justified.

- **NQF 0055: Diabetes Care Eye Exam.** KCP supports the directionality of this health plan-level measure. KCP is concerned, however, about the applicability of this measure only to patients aged 75 years and younger, since many dialysis patients fall outside this age range; we recommend the construct include patients aged 18 years and older. KCP also believes individuals who are blind in both eyes should be excluded. Finally, our review of the measure specifications reveals that the measure is identified as NQF 0055,

but the specifications presented for use in the CEC Initiative differ from those currently under endorsement maintenance review by NQF. Specifically, NQF 0055 (version under review) excludes patients with Polycystic Ovary Syndrome and steroid-induced diabetes, while the proposed CEC TEP measure does not. Additionally, NQF 0055 applies to all diabetic patients, regardless of appointment status, while the CEC TEP-proposed denominator only captures those diabetic patients with an appointment; these differences must be reconciled and justified.

- **NQF 0285: Rate of Lower Extremity Amputation Among Patients with Diabetes.** KCP does not support this measure. Amputations will be encompassed by the hospitalization measure(s); entities should not be penalized twice by such duplication. Our review of the measure specifications reveals that this is a risk-adjusted, general population-level measure that was not tested, nor endorsed, for use in the more complex ESRD population. We thus believe that the validity, reliability, and applicability of the current risk adjustment for this measure must be demonstrated in this population before the measure is adopted for use in the CEC Initiative. We also note that the specifications presented for use in the CEC Initiative differ from those currently under endorsement maintenance review by NQF. Specifically, NQF 0285 (version under review) has no exclusions, but the proposed CEC TEP measure excludes transfers from other hospitals, skilled nursing, intermediate care, or other health care facilities, as well as pregnant patients with any diagnosis of trauma. These differences must be reconciled, justified, and tested as they add additional complexity to an already complex risk adjustment model.

- **NQF 0089: Diabetic Retinopathy—Communication with the Physician Managing Ongoing Diabetes Care.** KCP supports the directionality of this physician-level measure. However, our review of the specifications reveals that the measure is characterized as being NQF 0089, but the specifications proposed for use in the CEC Initiative differ from the currently endorsed NQF measure. Specifically, NQF 0089 excludes patients for whom there is a medical or patient reason for not communicating the eye exam findings, while the proposed CEC TEP specifications have no exclusions. This discrepancy must be reconciled and justified.

- **NQF 0081: Heart Failure—ACE Inhibitor or ARB Therapy for LVSD.** KCP recognizes the potential importance of this measure for the ESRD population, but opposes inclusion of this measure in the CEC Initiative. KCP notes that this is a clinician-level measure tested and endorsed for the general patient population, but that it has not been tested nor endorsed for use in the more complex ESRD population. We believe the lack of such validation is especially problematic for pharmacotherapy measures, as there are insufficient data demonstrating that these specific therapies are of similar benefit in dialysis patients as in the general population.

  Our review of the specifications also reveals that the measure is represented as NQF 0081, but the specifications presented for use in the CEC Initiative differ from those currently under endorsement maintenance review by NQF. Specifically, NQF 0081 (version under review) excludes patients with a medical, patient, or system reason for not

prescribing the given medication, while the proposed CEC TEP specifications have no exclusions. This is a significant discrepancy that should be reconciled and justified.

- **NQF 0070: Coronary Artery Disease, Beta-Blocker Therapy for Prior MI or LVEF <40%.** Again, KCP recognizes the overall importance of this measure, but opposes its inclusion in the CEC Initiative, the focus of which is the more complex ESRD population. KCP notes that this is a clinician-level measure tested and endorsed for the general patient population. In fact, research studies underlying this measure excluded patients with ESRD, and the measure has not been tested nor endorsed for use in patients with ESRD. We believe the lack of such validation is especially problematic for pharmacotherapy measures, as there are insufficient data demonstrating that these specific therapies are of similar benefit in dialysis patients as in the general population. We also have concerns about this measure in the context of dry weight/fluid issues. Many patients with ESRD require significant fluid removal and can consequently experience significant hypotension during dialysis. We posit that these individuals should be excluded.

  KCP's review of the specifications reveals that the measure is stated as being NQF 0070, but the specifications presented for use in the CEC Initiative differ from those currently under annual update by the developer for NQF. Specifically, NQF 0070 (version under review) requires that patients have a history of prior MI or a current or prior LVEF <40% to be included in the denominator; yet the CEC TEP denominator captures all patients with CAD. The NQF measure excludes patients with a medical, patient, or system reason for not prescribing the given medication, while the proposed CEC TEP specifications have no exclusions—a significant deviation. Moreover, NQF 0070 also specifies which beta-blockers are appropriate for use in patients with LVEF <40% (i.e., bisoprolol, carvedilol, and sustained release metoprolol succinate), but the CEC TEP measure does not. These are significant deviations that should be reconciled and justified.

- **NQF 0043: Pneumococcal Vaccination Status for Older Adults.** KCP recognizes and supports the appropriate use of a pneumococcal vaccination measure in the CEC Initiative, but only if the measure is harmonized with the current recommendations of the Centers for Disease Control and Prevention for patients with ESRD.

  Additionally, KCP's review of the specifications reveals deviations from those endorsed by NQF. The denominator for NQF 0043 is derived from CAHPS survey responses, whereas it appears that the data for the measure proposed for the CEC Initiative are to be derived from EHRs as part of the EHR Incentive Program, and that the specifications from NQF 0043 have been converted to e-specifications with a denominator population not limited to responses through the CAHPS survey, though we found it difficult to decipher the precise boundaries. As we have indicated, greater articulation and transparency should be utilized rather than simply referring to an NQF number.

- **NQF 0028: Tobacco Use: Screening and Cessation Intervention.** KCP supports this clinician-level measure for use in the CEC Initiative. However, our review of the specifications reveals deviations from the NQF-endorsed specifications. Specifically, the

denominator for NQF 0028 is "All patients aged 18 years and older *who were seen twice for any visits or who had at least one preventive care visit during the two-year measurement period.*" The specifications for the measure proposed for use in the CEC Initiative are "All patients aged 18 years and older." This deviation should be reconciled and justified.

- **NQF 0418: Screening for Clinical Depression and Follow-up Plan.** KCP is acutely sensitive to the importance of clinical depression in ESRD patients, and notes that mental health is always an issue with chronic illness. When evaluated by the MAP, KCP opposed use of this measure for the QIP because, among several reasons, it was endorsed as a clinician-level measure. We also have concern about the impact of "check-box" measures such as this one. KCP also is concerned about the lack of a tool for ESRD and effective intervention. Nevertheless, as applied in the broader context of the CEC Initiative, KCP supports this measure.

- **NQF 0326: Advance Care Plan.** KCP supports this clinician-level measure in principle, but believes the denominator limitation of patients 65 and older is too limiting. We recommend that the denominator be changed to patients 18 years and older.

- **NQF 0419: Documentation of Current Medications in the Medical Record.** KCP supports this clinician- and population-level measure.

- **Functional Status Assessment of Complex Chronic Conditions.** KCP recognizes the importance of assessing patients' functional status, however, we oppose inclusion of this measure in the CEC Initiative. First, we note the measure is not NQF-endorsed, a general pre-requisite for KCP to support inclusion. Second, the denominator population for this measure is limited to patients aged 65 years and older with two active encounters and an active diagnosis of heart failure, so it is clearly a measure developed for other purposes (and because it has not been endorsed, we have no information on reliability and validity information). We also note that CMS recently called for nominations for a TEP to develop a functional assessment measure for the ESRD population—tacit acknowledgment that this population needs a unique and appropriate instrument.

- **NQF 0059: Diabetes Care Hemoglobin A1c Poor Control.** KCP does not support this measure for inclusion in the CEC Initiative. KCP notes that this is a clinician-level measure tested and endorsed for the general patient population that has not been tested nor endorsed for use in the more complex ESRD population. We believe the lack of such validation is problematic and question the applicability of this measure for the ESRD population. We further note that HbA1c monitoring is intended to help <u>prevent</u> diabetic end-organ complications. In most cases, patients with ESRD who have diabetes already have one or more of these complications (i.e., renal failure); it is thus unclear that HbA1c testing is an appropriate tool or that working to achieve a specific HbA1c target range is a beneficial or universally warranted endeavor in this patient population.

  KCP also notes that the measure is referred to as 0059, but the specifications presented differ from those currently under endorsement maintenance review by NQF. Specifically, NQF 0059 excludes patients with Polycystic Ovary Syndrome and steroid-induced diabetes, while the corresponding CEC TEP measure does not. And unlike the

CEC TEP measure, NQF 0059 captures patients with missing results and those who did not have HbA1c testing during the measurement period in the numerator. These discrepancies must be reconciled and justified.

- **NQF 0083: Heart Failure, Beta Blocker Therapy for LVSD.** KCP recognizes the general importance of this measure, but does not support its inclusion in the CEC Initiative. KCP notes that this measure was tested and endorsed for the general patient population, but has not been tested nor endorsed for use in the more complex ESRD population. We believe the lack of such validation is especially problematic for pharmacotherapy measures, as there is insufficient data demonstrating that these specific therapies are of similar benefit in dialysis patients as in the general population. Additionally, we note that beta-blockers are contraindicated in asthmatic patients and in patients with moderate to severe COPD, and should be used with caution in patients prone to bradycardia. This is of particular importance in dialysis patients, in whom tachycardia can be a necessary physiologic response to volume loss. The measure exclusions do not reflect these concerns.

  KCP reviewed the specifications represented as being NQF 0083 for use in the CEC Initiative, and found they differ from those currently under annual update by the developer for NQF. Specifically, NQF 0083 excludes patients with a medical, patient, or system reason for not prescribing the given medication, while the proposed CEC TEP specifications have no exclusions. NQF 0083 also specifies which beta-blockers are appropriate for use in patients with LVEF <40% (bisoprolol, carvedilol, and sustained release metoprolol succinate), but the CEC TEP measure does not. These discrepancies must be reconciled and justified.

- **NQF 0068: Ischemic Vascular Disease, Use of Aspirin or Another Antithrombotic.** KCP recognizes the general importance of this measure, but does not support its inclusion in the CEC Initiative. This measure was not tested nor endorsed for use in the ESRD population. Given the current absence of data demonstrating that antithrombotics have the same benefit(s) and safety profile in dialysis patients as in the general population, we have concerns about its broad application to all ESRD patients. This is of particular importance with antithrombotics, as dialysis patients already typically receive heparin thrice weekly and are at increased risk for bleeding during the dialysis procedure.

  Our review of the specifications reveals the denominator statement has been modified slightly from the NQF-endorsed measure. We believe its intent is likely for the purpose of capturing the timeframe for inclusion slightly differently, but again posit that in the interest of transparency CMS should present redlined specifications and acknowledge and justify the change.

- **NQF 1789: Hospital-Wide All-Cause Unplanned Readmission Measure.** KCP does not support inclusion of this measure in the CEC Initiative, viewing it as redundant with other proposed measures.

- **NQF 0097: Medication Reconciliation.** KCP supports the inclusion of this measure in the CEC Initiative.

- **KDQOL; no NQF number provided, but we are aware KDQOL is NQF-endorsed (0260).** KCP recognizes the importance of assessing the health-related quality of life for individuals with ESRD. Nevertheless, we have opposed use of the KDQOL in the ESRD QIP and, likewise, oppose its use as a CEC Initiative measure for numerous reasons: 1) Annual administration of the KDQOL is already required under the Conditions for Coverage; KCP questions how enactment of a measure for a process that is already required and surveyed will further improve patient care; 2) Absent validation at the patient-level or risk/case-mix adjustment, KCP believes the KDQOL will not provide valid information on care coordination and is thus not an appropriate measure for use in the CEC Initiative; 3) KCP notes that the KDQOL-36 is NQF-endorsed (NQF 0260); however, the CEC TEP specifications indicate that an NQF number is "not applicable" for this measure, bringing into question whether what is being proposed for use in the CEC Initiative is in fact the NQF-endorsed measure; 4) KCP notes that the KDQOL was originally validated on 165 patients in 1997.[2] As dialysis patients are known to have a different disease burden today than 17 years ago, we believe the instrument should be validated in a larger, more contemporary dialysis population.

  Again, in our review of the specifications, we note that the KDQOL-36 is NQF-endorsed (NQF 0260), however, the proposed CEC TEP specifications indicate that an NQF number is "not applicable" for this measure, bringing into question whether this is in fact the same measure. The exclusions listed in the CEC TEP specifications are consistent with the NQF-endorsed specifications, but because a numerator and denominator are not provided in the materials, it is unclear whether it is the same as the NQF-endorsed measure, which assesses the percentage of eligible patients who completed the KDQOL-36 at least once yearly. Because it is unclear what portions of the KDQOL will be used and deployed in the CEC Initiative, it is also unclear whether the information gleaned from the survey will be actionable. Specifically, if the intended use is to follow consecutive survey scores for improvement over time, KCP has commented previously that we are unaware of any peer-reviewed evidence indicating that interventions undertaken as part of dialysis care result in clinically important or statistically significant changes in the domains reflected in the survey score.

- **NQF 0369. Dialysis Facility Risk-Adjusted Standardized Mortality Ratio (SMR).** KCP has on several occasions expressed concern about the SMR because of a lack of transparency in the methodology and lack of published validation studies. We also note that we applauded CMS for recognizing in 2013 that before it can adopt the SMR for use in the QIP, CMS needed to "properly take[s] into account the effect that comorbidities have on hospitalization and mortality rates in the ESRD population."[3] However, notwithstanding KCP's concerns about the SMR, we believe the CEC Initiative can

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[2] Mayne T, Dunn D, Marlowe G, Schatell D. Revalidation of the Kidney Disease Quality of Life Questionnaire (KDQOL). *Davita, Inc. Denver, CO; MEI, Madison, WI.* Abstract presented at ASN's 2010 Renal Week. https://www.asn-online.org/. *Last accessed January 16, 2014.*

[3] "End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; Proposed Rule" 78 *Fed. Reg.* 40836, 40861 (July 8, 2013).

improve survival and so in principle support including a mortality measure—e.g., an unadjusted rate, subject to sample size and appropriate attribution, that focuses on a year-over-year, facility-specific improvement. Absent using such a measure, we recommend that this measure be used only on a descriptive basis and also that it be paired with a raw number.

- **Standardized Readmission Ratio for Dialysis Facilities; unassigned, but under review in current project.** KCP recognizes the importance of assessing readmissions, but has serious reservations about this measure. We have previously commented at length regarding our concerns about using this measure in the QIP, including but not limited to: a methodology that is not transparent; the lack of adequate risk adjustment for hospital-specific patterns and a complete lack of physician-level factors; the inclusion of all causes; the incorporation (or lack thereof) of certain conditions in the risk model; and the lack of demonstration that no bias exists between urban and rural hospitals. In the context of using this measure in the CEC Initiative, we have concerns about the denominator population as being ill-defined. Finally, we have strong concerns overall about the lack of validation, given that CMS intends to conduct a dry-run for this measure in 2014.

  Nevertheless, given the importance of reducing hospitalizations and readmissions to achieving savings, KCP acknowledges that metrics related to readmissions are important—but we also maintain that a scientifically validated measure is important. Absent that, we suggest that, at minimum, if this measure is used, that it be done on a descriptive basis and also that it be paired with a raw number (e.g., as is currently provided in Dialysis Facility Reports) or that an unadjusted rate that focuses on a year-over-year, facility-specific improvement be used.

- **NQF 1463. Standardized Hospitalization Ratio for Admissions (SHR).** KCP has on several occasions expressed concern about the SHR measure because of a lack of transparency in the methodology and published validation studies. We also note that we applauded CMS for recognizing in 2013 that, before it can adopt the SMR for use in the Quality Incentive Program, CMS needed to "properly take[s] into account the effect that comorbidities have on hospitalization and mortality rates in the ESRD population."[4] We also have concern about the effect of local hospital practices—i.e., community resources may have an impact that may not be comparable. KCP believes that this measure may be useful for a descriptive purpose, but given the lack of validation, has concerns about its use as a performance measure in the CEC Initiative. We recommend a metric that focuses on year-over-year, facility-specific improvement.

- **NQF 0041/0226: Influenza Immunization.** KCP supports inclusion of an influenza measure in the CEC Initiative, but opposes NQF 0041. KCP supports NQF 0226, which aligns with the Neff's standardized specifications for influenza immunization measures and is endorsed for the ESRD population. NQF 0041 is not aligned with the NQF-standardized specifications, and its exclusions are poorly constructed from a

[4] *Id.*

technical standpoint. Specifically, not only are the exclusions inconsistent with the NQF's specifications, they use an "e.g.," construction that could be broadly misinterpreted and/or applied variably by different users, making accurate comparisons impossible.

- **Anemia of Chronic Kidney Disease (Standardized Transfusion Ratio).** KCP does not support including this measure in the CEC Initiative. First, we do not believe it is clinically meaningful. Second, it is not NQF-endorsed. Third, it has not been validated. Finally, KCP has several significant concerns and questions about the specifications. The documentation makes reference to a comorbidity index, but it is not entirely clear about the details. The STrR does not adjust for hospital- or physician-related factors. The literature notes that both hospital and physician factors impact transfusion rates in other areas; there is no reason to think transfusions related to ESRD patients are any different. We also are concerned with the approach and assumptions for the predictive model that posits to reveal an actual versus predicted rate when the basis for the ratio comes from claims data and not EMR data. The documentation fails to demonstrate that the measure accurately predicts and identifies those who have had transfusions. Additional analytic rigor must be brought to bear for this measure.

III. Conclusion

We appreciate the opportunity to comment. KCP strongly believes that a more effective and efficient approach to measure identification for Medicare programs requires a change in the TEP process that would result in greater transparency and increased flexibility. Thus, as a first step, we encourage CMS and its contractors to collaborate with KCP and leverage our experience as a measure developer through KCQA to engage the community in a more meaningful process for measure development.

In terms of the specific measures, we welcome the opportunity to discuss our concerns in more detail with the Agency and IMPAQ. Before they are finalized, we once again urge CMS to solicit stakeholder comments given the magnitude of the issues that need to be resolved.

Thank you for your consideration of our comments and recommendations. Please do not hesitate to contact Kathy Lester at (202) 534-1773 or klester@lesterhealthlaw.com if you have any questions.

Sincerely,

Edward R. Jones, M.D.
Chairman
Kidney Care Partners

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