KIDNEY CARE PARTNERS

August 19, 2013

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Director and Chief Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Via Email: ESRD_Quality_Measures@ArborResearch.org

Dear Dr. Conway:

Kidney Care Partners (KCP) appreciates the opportunity to comment on the proposed quality measures for bone and mineral disorder, pediatric peritoneal adequacy, hemodialysis adequacy, and preventive care for the End-Stage Renal Disease (ESRD) population. As you know, KCP is an alliance of members of the kidney care community that includes patient advocates, physicians, nurses, dialysis facilities, providers, and manufacturers. We greatly appreciate your extension of the comment period from August 12 to August 19. And while KCP continues to have significant concerns about most of the measures and, in particular the measure development process in its current form, we remain committed to continuing to work with CMS to identify a process that will lead to the development of meaningful, evidence-based, reliable and valid measures that can be used to assess and improve the quality of care for patients with ESRD.

We have reviewed the draft measures that were developed by Arbor Research/UM-KECC and its technical expert panels (TEPs) and provide the following comments on behalf of the KCP members listed in Appendix A. Please note that KCP's lack of comments on the specifications for a given measure should not be construed as support for the specifications; in the vast majority of cases, the lack of testing data does not even permit evaluation. Additionally, our comments and recommendations focus on the clinical and technical aspects of a measure; they do not address how such measures should be integrated in the Medicare End Stage Renal Disease (ESRD) Program. Specifically, these comments and recommendations should not be viewed as endorsing any of these measures for use in the ESRD Quality Incentive Program (QIP). Our goal is to provide CMS with information to improve these measures. Once a measure has been appropriately developed, specified and tested, a separate review should take place to determine its appropriate use in terms of surveillance, public reporting or quality payment. Overall, our comments are as follows:

- KCP cannot evaluate the majority of proposed measures because essential information is missing. Specifically, reliability and validity testing information for 10 of the 15 proposed draft measures is not available or is asserted as not necessary.
- KCP opposes advancing the proposed influenza measure, *ESRD Vaccination—Full Season Influenza Vaccination,* and recommends CMS conform with the re-evaluation/reconsideration options in the context of the National Quality Forum (NQF) endorsement process.

- For the five measures for which testing data were provided: KCP opposes the *Hemodialysis adequacy: Ultrafiltration Rate > 13 ml/kg/hr* measure as currently presented; recommends changes to *Mineral and bone disorder: Percentage of all peritoneal dialysis and hemodialysis patients with uncorrected serum calcium measured at least once within a month* and *Mineral and bone disorder: Measurement of Serum Phosphorus Concentration (NQF #0255)*, and supports *Pediatric peritoneal dialysis adequacy: Achievement of Target Kt/V* and *Pediatric peritoneal dialysis adequacy: Frequency of Measurement of Kt/V*.
- KCP continues to have significant concerns about the CMS measure development process that CMS should address before proceeding with further measure development.

I. KCP is unable to evaluate the majority of proposed measures because essential information is missing. Specifically, reliability and validity testing information for 10 of the 15 proposed draft measures is not available or is asserted as not necessary.

As CMS is aware, NQF requires testing data before it will consider measures for endorsement because it considers the criterion "Scientific Acceptability"—i.e., validity and reliability—to be an essential component of a measure's properties. Yet the Measure Information and Measure Justification Forms for 10 of 15 measures proposed do not provide this information.

NQF describes reliability and validity testing at either the data element level or the level of the computed measure score, as follows:

> Reliability of data elements refers to repeatability and reproducibility of the data elements for the same population in the same time period. Validity of data elements refers to the correctness of the data elements as compared to an authoritative source. Reliability of the measure score refers to the proportion of variation in the performance scores due to systematic differences across the measured entities (or signal) in relation to random error (or noise). Validity of the measure score refers to the correctness of conclusions about the quality of measured entities that can be made based on the measure scores (i.e., a higher score on a quality measure reflects higher quality).

Merely the fact that data elements must be reported does not mean they can be reliably reported; CMS must demonstrate this. Moreover, and more importantly, the NQF measure testing guidance notes that even if data elements can be reliably reported, it does not necessarily follow that they are indicative of, or have an impact on, health care quality—i.e., that they are valid.

We are particularly troubled by the apparent assertion that validity and reliability testing data are not applicable for certain measures because they are "reporting measures" ("N/A—Reporting measure"). If it wishes to proceed with these measures, CMS should demonstrate that the specified data can be reliably reported pursuant to NQF's measure testing guidance. Additionally, it should validate that reporting of the data per se as a measure is valid from a quality perspective. The notion that testing of the reporting measures is not applicable fails to recognize the purpose of validity and reliability testing.

Because we can assess neither reliability nor validity for the following measures, we request the requisite testing information be obtained and additional public comment be sought before they are further advanced for any purpose (e.g., NQF endorsement or implementation by CMS).

1. Hemodialysis adequacy: Surface Area Normalized Standard Kt/V Reporting Measure

2. Hemodialysis adequacy: Standard Kt/V Reporting Measure
3. Preventive care: ESRD Vaccination – Full-Season Influenza Vaccination
4. Preventive care: ESRD Vaccination – Timely Influenza Vaccination
5. Preventive care: ESRD Vaccination – Influenza Vaccination of Dialysis Facility Healthcare Personnel
6. Preventive care: ESRD Vaccination – Pneumococcal Vaccination (PCV13)
7. Preventive care: ESRD Vaccination – Lifetime Pneumococcal Vaccination
8. Preventive Care: ESRD Vaccination – Pneumococcal Vaccination (PPSV23)
9. Mineral and bone disorder: Percentage of Dialysis Patients with Dietary Counseling
10. Mineral and bone disorder: Measurement of Plasma PTH Concentration

As noted in the following section, we provide further comment regarding *Preventive care: ESRD Vaccination – Full-Season Influenza Vaccination.*

II. KCP opposes advancing the proposed full season influenza vaccination measure, which is not aligned with the NQF-endorsed standardized specifications for influenza immunization measures. CMS should request deviation from the standardized specifications via an NQF renal maintenance review project or through an ad hoc review.

KCP opposes advancing the proposed influenza measure *ESRD Vaccination—Full Season Influenza Vaccination*, and believes that CMS should more appropriately work within the NQF rubric to seek modifications it wishes to pursue. First, we object to the assertion that the measure is "harmonized" with the standardized specifications from the 2008 NQF report: It is not. This measure adds patient death as an exclusion and does not follow the NQF measurement timeframe of October 1 through March 31 or whenever the vaccination is first available. Second, KCP supports the current NQF-endorsed measure (#0226 *Influenza Immunization in the ESRD Population*), which does align with NQF's standardized specifications for influenza and pneumococcal vaccinations—a project undertaken at the behest of and funded by CMS to address the plethora of care site-specific, varying specifications.[1] As part of the Population Health/Prevention Maintenance project, NQF #0226 was most recently reviewed in early 2013 against the standardized specifications and found to comport with them, and its NQF endorsement was maintained.

We recognize measurement specifications, like evidence, evolve. However, we believe CMS and the kidney care community are best and most efficiently served if CMS conforms to existing NQF processes to address full-season influenza vaccination. Specifically, if CMS believes the evidence supports the additional exclusion of patient death or refinement of the measurement timeframe, it should work with the measure developer, the Kidney Care Quality Alliance (KCQA), and use the NQF endorsement maintenance process to request that NQF #0226 deviate from the standardized specifications or that the standard specifications themselves be updated. If CMS believes an exigency exists, it could request that NQF conduct an ad hoc review.

Finally, we note that the dates contained in the measure description differ from those specified in the numerator—October 1-March 31 and August 1-March 31, respectively. One or the other needs correction.

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[1] National Quality Forum. *National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations: A Consensus Report.* Washington, DC, 2008. www.qualityforum.org. Last accessed August 8, 2013.

III. Five measures provided testing data: *Hemodialysis adequacy: Ultrafiltration Rate > 13 ml/kg/hr; Mineral and bone disorder: Percentage of all peritoneal dialysis and hemodialysis patients with uncorrected serum calcium measured at least once within a month*; *Mineral and bone disorder: Measurement of Serum Phosphorus Concentration (NQF #0255)*; *Pediatric peritoneal dialysis adequacy: Achievement of Target Kt/V;* and *Pediatric peritoneal dialysis adequacy: Frequency of Measurement of Kt/V*. The following sections provide KCP's comments for each of these five measures.

A. KCP opposes the measure *Hemodialysis adequacy: Ultrafiltration Rate > 13 ml/kg/hr*.

KCP opposes this measure for multiple reasons. First, the current literature of three observational studies does not rise to a level of evidence to support a performance measure. By CMS' own admission on the Measure Justification Form, the value of >13 ml/kg/hr was selected as a compromise among eight individuals and is not grounded by scientific rigor.

Additionally, we note that recent research has examined ultrafiltration rate linearly in relation to body size.[2] Preliminarily, this study has found that at the high end there was a preponderance patients with small body size and at the low end patients had a preponderance of large body size. A logical conclusion of these findings is an uncertainty that rate of removal is the appropriate measurement of quality—i.e., they reinforce our concern that the evidence does not support the proposed measure.

Finally, we note that examining the quality of hemodialysis adequacy has always focused historically on small solute removal. Examining an ultrafiltration rate measure under the guise of a Technical Expert Panel (TEP) convened to examine hemodialysis adequacy is unconventional, at best, and at worst an abrogation of the process in order to circumvent the previous work and expertise of the Fluid Management TEP—a group that was more appropriate to examine any measure of ultrafiltration rates and that did not recommend such a measure.

B. KCP continues to have concerns about *Mineral and bone disorder: Percentage of all peritoneal dialysis and hemodialysis patients with uncorrected serum calcium measured at least once within a month* and *Mineral and bone disorder: Measurement of Serum Phosphorus Concentration (NQF #0255)* as appropriate quality measures. We also recommend plasma be added as an acceptable assay substrate.

KCP recognizes the importance of mineral and bone disorder measurement as a component of high-quality care for patients with ESRD. While we did not object to the inclusion of these measures in the Quality Incentive Program (QIP) for payment year 2015, we continue to be concerned that they do not meaningfully represent quality of care for ESRD patients.

If the measures are to continue, we also believe the proposed measure specifications do not represent industry-accepted measurement equivalency of either serum or plasma as the substrate. Moreover, plasma testing is more patient-centered, since it requires less blood. Accordingly, KCP

[2] Abstract accepted for poster presentation, American Society of Nephrology, November 2013. Currently under ASN embargo.

recommends that the specifications be modified to indicate either monthly serum or plasma testing is permitted.

We are aware that at least one renal laboratory, Ascend Clinical, has been using plasma testing since 2006. Others (e.g., Spectra Laboratories) are considering it because, as just noted, it is more patient-centered. Additionally, plasma is more stable and requires less manipulation should additional testing be required. Serum and plasma testing have been validated for most clinical chemistry analyzers, with both deemed acceptable and equivalent[3] by analyzer manufacturers. Unpublished data from Spectra Laboratories provided to a KCP member found there was virtually no difference between phosphorus measured in serum vs. plasma: a difference of 0.01 mg/dL; phosphorus values are reported to the nearest 0.1 mg/dL. And although some reported differences in serum phosphorus vs. plasma measurement occur, i) such differences are within the College of American Pathologists total allowable error; and ii) such differences could not be replicated by two large experiments conducted by Spectra Laboratories.

Finally, we also object to the characterization in the Measure Justification Forms that the Prevention TEP definitively opposed inclusion of plasma as a substrate. KCP members in attendance understood the TEP to demure on the issue, stating a general lack of expertise in laboratory issues and recommending that a separate laboratory-focused TEP consider the request.

C. KCP supports *Pediatric peritoneal dialysis adequacy: Achievement of Target Kt/V;* and *Pediatric peritoneal dialysis adequacy: Frequency of Measurement of Kt/V*.

KCP supports both pediatric peritoneal dialysis measures as presented.

IV. KCP continues to have significant concerns about the CMS measure development process that CMS should address before proceeding with further measure development. Given the overarching concerns that the community has expressed with regard to the TEP process for the past several years, we also encourage CMS to open the bidding process for selecting the contractor that oversees it going forward.

KCP continues to have significant concerns about the process used to develop the 15 measures for which comment has been sought. First, concerns remain as to the constitution of the individual TEPs. Many members of KCP continue to express concerns that the day-to-day operations of dialysis facilities are not being discussed or considered in a meaningful manner during these discussions. Second, the process seemed pre-determined to advance proposed measures, as opposed to an open process for responding to comments and recommendations of TEP members. Third, the process was rushed, including this request for comment and the lack of testing data for 10 of the 15 measures. It was a suboptimal process that led to a suboptimal result.

KCP maintains its recommendation that CMS revise its TEP process to be more transparent and open to the entire kidney care community. Specifically, we request that CMS:

- Share the agenda and other materials to interested stakeholders broadly through the CMS website prior to the TEP meeting;

[3] Boyanton Jr BL and Blick KE. Stability studies of twenty-four analytes in human plasma and serum. *Clin Chem.* 2002;48(12):2242-2247; Wei Y, Zhang C, Yang X, et al. The feasibility of using lithium-heparin plasma from a gel separator tube as a substitute for serum in clinical biochemical tests. *Lab Med.* 2010;41(4):215-219.

- Provide for a more open process by allowing non-TEP members to listen in on the TEP work group calls and provide comments at the end of these calls and in writing via email to the CMS staff member coordinating the particular group, to also be shared with TEP members;
- Increase transparency in the TEP grading criteria by having overt grading by each panel member and identification of these results.
- Provide TEP members all measure comments received through this process for discussion on work group calls and permit non-TEP members to participate through a public comment period in such calls;
- Create a transparent framework for how population measures should be created and ensure that participants consider measures at the population level;
- Require TEPs to review data from the dialysis unit level in addition to data from large randomized controlled trials/national aggregated data so that measures that are to be used at the facility level will be developed with such data;
- Instruct 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 quality of life for patients), and their appropriateness for being reported and and/or incorporated into the ESRD QIP;
- Include patients and their advocates in the process, as well as non-physicians, to ensure that any measures developed represent consensus from the entire community;
- Reinstitute the Data TEP into each TEP process, which will allow for a second level of review and consideration of all relevant aspects of the data requirements for a particular measure; and
- Publicly post 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. (We were pleased to note all comments will be available, but it is unclear if a response to each will be provided, as NQF does.)

Given the overarching concerns that the community has expressed with regard to the TEP process for the past several years, we also encourage CMS to open the bidding process for selecting the contractor that oversees it going forward.

V. Conclusion.

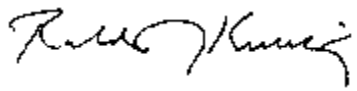
We appreciate the opportunity to comment and strongly believe that a more effective and efficient approach to measure development requires a change in the TEP process that would result in greater transparency and increased flexibility. We also believe a more robust measure development process would have resulted in proposed measures that would not have had the series of unresolved issues we have identified. Thus, as a first step, we encourage CMS and the measure developer to collaborate with KCP and leverage its experience as a measure developer through KCQA and 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. 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) 457-6562 or klester@pattonboggs if you have any questions.

Sincerely,



Ronald Kuerbitz
Chairman
Kidney Care Partners

cc: Jean Moody-Williams
Kate Goodrich
Joel Andress

Appendix: KCP Members

AbbVie
Affymax
American Kidney Fund
American Nephrology Nurses' Association
American Renal Associates, Inc.
American Society of Nephrology
American Society of Pediatric Nephrology
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
Dialysis Clinic, Inc.
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Kidney Care Council
Mitsubishi Tanabe Pharma America
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
Sanofi
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care