KIDNEY CARE PARTNERS

May 2, 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 hospital readmission and anemia management measures for the End-Stage Renal Disease (ESRD) population and the Agency's extension of the comment deadline. 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. KCP is prepared to continue working with CMS to develop measures that will be used to assess and improve the quality of care for Americans with ESRD.

I. CMS should provide additional clarity and make specific modifications to the hospital readmission and anemia management measures before finalizing them

We have reviewed the draft measures that were developed by Arbor Research/UM-KECC and its technical expert panels (TEPs). Our comments and recommendations focus on the clinical and technical aspects of each 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 and specified, a separate review should take place to determine its appropriate use in terms of surveillance, public reporting, or quality payment.

Additionally, it is critically important that to the extent CMS modifies these measures to address the specific concerns below, it must also provide transparency as to the development and adoption of the benchmarks used to evaluate performance with these measures. The benchmarks need to be established using the most current data available. Relying on older data would not present an accurate or clinically appropriate view of a facility, and reliance on these data by patients would make it extremely difficult, if not inappropriate, for people living with kidney failure who receive life-sustaining dialysis treatments to utilize these measures when making decisions.

A. Standardized Unplanned 30-Day Readmission Ratio for Dialysis Facilities (SRR)

KCP has several significant concerns and questions about the specifications as currently drafted. Given our concerns, as well as those expressed by members of the TEP during the discussion of this measure, we strongly recommend a more evidence-based approach to the refinement of this measure. As currently defined, it is not appropriate for use.

First, the SRR as specified is inconsistent with the *Dialysis Facility Risk-Adjusted Standardized Mortality Ratio* measure and the *Standardized Hospitalization Ratio for Admissions* measure. These measures include only patients who have had ESRD for 90 days or more. The proposed SRR measure does not appear to be harmonized with these measures in this respect. CMS should clarify why this difference is present and provide the data analysis on the implications of this difference.

Second, KCP notes that the specifications submitted to the National Quality Forum's (NQF) Measure Applications Partnership (MAP) had an exclusion for "index hospitalizations that occur after a patient's 6th readmission in the calendar year," which has now been revised to those that "occur after a patients 12th readmission in the calendar year." We believe the developer should be transparent about this change. In particular, KCP is concerned about the impact of this change on low volume facilities, and believe it imperative for the measure developer to report on the underlying distribution that led to this change in order to understand its implications as compared to the MAP version.

Third, we note that the *Hospital-Wide All-Cause Unplanned 30-Day Readmission Ratio* excludes patients who have incomplete claims history from the past year, but the proposed dialysis facility SRR does not. The measure developer should provide the data on readmission rates for patients who have a full year of claims versus those who do not, as well as data on the impact of such an exclusion on the sample size and performance gap. Such data and analyses are necessary in order to understand why the current measure is not and/or should not be harmonized with the hospital measure.

Fourth, we recommend the risk model also include sickle cell trait, not just sickle cell anemia, as well as angiodysplasia, myelodysplasia, diverticular bleeding, and asthma, as well as adjust for nursing home status. Additionally, we note that "poisoning by nonmedical substances," is included, but request clarification if this encompasses ongoing/chronic alcohol or drug abuse and not just acute events.

Fifth, KCP believes the model fails to adequately account for hospital-specific patterns and fails to adjust at all for physician-level admitting patterns—in particular because the decision to admit/readmit is a physician decision. Geographic variability in this regard is well documented in other areas, and there is no reason to believe the situation is different for ESRD patients. Specifically, merely adjusting for the hospital as a random effects variable is insufficient. Recent research indicates that beyond a simple hospital ranking, broader regional and geographic variability persists and must be accounted for.

Sixth, KCP continues to strongly recommend that the measure be limited to those readmissions that are related to or actionable to ESRD rather than the all-cause specifications promulgated in the current draft. Data from one KCP member reveal that approximately 45 percent of readmissions are not related or actionable; moreover, only a subset of the 55 percent attributable ESRD admissions are same cause-specific readmissions.

Seventh, KCP recommends that patients who are readmitted in the first 1-3 days after discharge be excluded from the measure. Data from two KCP members find that among patients who were rehospitalized within 30 days of the initial hospitalization in 2011, 11-17 percent of patients were readmitted during this period, often even before the first outpatient dialysis encounter. Specifically, for one KCP member, 17 percent of patients are readmitted within 3 days post discharge, among whom only 35 percent of patients had been seen by the dialysis unit prior to the readmission. In other words, by an approximately 2:1 margin, rehospitalized dialysis patients had not been seen by the dialysis facility before readmission. Penalizing facilities for such situations is patently unreasonable. Further in this regard, during the first 8 days after discharge, up to 40 percent of patients were readmitted—again the dialysis center has had a limited number of encounters to intervene/affect quality of care.[1] Lastly, not all discharges are to home and a significant number of patients are readmitted before they receive care from a dialysis facility. The measure should account for this.

Eighth, the developer should provide data to demonstrate there is no bias of the SRR between rural and urban facilities; this is not simply adjusted for by the hospital as a random effect variable. KCP notes that the distance of a patient's home relative to the outpatient facility and to the hospital likely influences their choices for care, and it likely further influences their utilization of care, particularly if there are symptoms that occur on non-dialysis days. The co-pay for transportation also may influence health utilization behavior. It is important for the measure developer to evaluate the impact of these factors on readmission rates for patients with ESRD and report in the Measure Justification Form why such factors should or should not be incorporated. We posit that billing data may shed light on how to evaluate these factors, yet they were not even considered.

Overall, we 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.

In sum, CMS has at its disposal the data to address a number of these issues—specifically the ability to understand the types of readmissions that dialysis patients experience, the length of time post-discharge when readmissions occur in relationship to when outpatient dialysis unit care resumes, the sites of service that patients are discharged to, and claims data related to physician admission/readmission for purposes of adjusting the model for this factor. We recognize it is difficult work, but it is not impossible given the data available to CMS. We strongly recommend a more evidence-based approach to this measure.

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[1] *See* Kevin E. Chan, J. Michael Lazarus, et. al, "Association between repeat hospitalization and early intervention in dialysis patients following hospital discharge," 76 *Kidney Internat'l.* 331-43 (2009).

B. Patient Informed Consent for ESA Treatment

As a threshold matter, it is impossible to assess this measure without specific details. The Measure Information Form reports the numerator and denominator details are to be determined. In addition, informed consent is a very specific term-of-art and the risk-benefit discussion should occur between the physician and the patient. The Food and Drug Administration already has in place a REMS that requires the physician and patient to discuss the use of ESAs. An informed consent process would not be consistent with the current process and could lead to significant confusion among patients. This measure is not appropriate as a facility-level measure. Finally, it is KCP's understanding that this measure was not discussed or proposed at the in-person TEP meeting. We object that this measure has even been advanced for comment if such is the case.

C. Standardized Transfusion Ratio (STrR)

KCP has several significant concerns and questions about the specifications as currently drafted. First, the documentation makes reference to a comorbidity index, but it is not entirely clear about the details. Is the developer referring to the Charlson Comorbidity Index?

As with the SRR, 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. The developer should review CMS's data and document why the risk model should not account for these variables—i.e., the burden is on the developer to conduct the analyses and show that accounting for hospital-level and physician-level factors is not important in this area. Such details are particularly important because facilities do not have access to transfusion data; the Measure Justification and Measure Information Forms must therefore provide transparency.

Also, and as with the SRR, we 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 it accurately predicts and identifies those who have had transfusions. Additional analytic rigor must be brought to bear for this measure.

D. ESA Management to Avoid Transfusion

KCP has several significant concerns and questions about the specifications as currently drafted. First, the specifications submitted to the NQF's MAP excluded patients receiving dialysis <90 days, but the proposed measure does not. The developer should be transparent about this change and provide data related to incorporating the exclusion vs. not incorporating it so that the implications of the shift can be assessed. Similarly, the same should be done for the exclusion of patients who received more than one type of ESA or dialysis during both the reporting month and the subsequent month, which was in the MAP version of the measure but not the proposed draft specifications.

Second, the evidence basis for defining a "low dose" as <75 units/kg per session of Epoetin alfa or <25 mcg/kg per session of Darbepoetin alfa is unsupported. KCP is not aware of any trials

supporting a specific dose threshold for everyone and so believes the measure lacks an evidence base for the specifications.

Finally, it is KCP's understanding that this measure also was not discussed or proposed at the in-person TEP meeting. As with the informed consent measure, we object that this measure has even been advanced for comment if such is the case.

E. Hemoglobin >12g/dL

KCP has significant concerns and questions about the specifications as currently drafted. First, this measure differs from the measure in current use by changing the reporting period from 12 to 3 months and the required valid claims from 4 months to 1 month. It also requires at least 2 months with a valid, non-missing Hgb. In doing so, KCP notes that greater clarity with respect to the verbiage "3-month reporting period" must be provided.

Our understanding is that the values are not identified based on 3-month rolling averages. Rather, it appears that there are four 3-month reporting periods that produce four values. What is not specified, however, is whether those four values are then averaged to produce an average value for the full performance year. The developer should clarify whether each 3-month data point counts individually as "Successful"/"Not Successful," if some algorithm or point scale will be applied based on how far off 12 g/dL the value is for each quarter and then rolled up to a composite for the performance year, or if it is in fact a 3-month rolling average.

Second, the developers cite the 2010 paper by Hirth *et al.* as evidence that greater variation exists in facility anemia management as compared to physicians. KCP believes the developer should demonstrate and report results that demonstrate that the new measure will have a meaningful impact as compared to results using the existing specifications. Merely reporting results using the new specifications and positing that they will, hypothetically, result in improved management is insufficient to justify the burden of re-tooling current systems.

F. Hemoglobin <10 g/dL

KCP has significant concerns and questions about the specifications as currently drafted. This measure, like the Hgb >12 g/dL measure, refers to a 3-month reporting period. Our understanding is that the values are not identified based on 3-month rolling averages. Rather, it appears that there are four 3-month reporting periods that produce four values. What is not specified, however, is whether those four values are then averaged to produce an average value for the full performance year? The developer should clarify whether each 3-month data point counts individually as "Successful"/"Not Successful," if some algorithm or point scale will be applied based on how far off 12 g/dL the value is for each quarter and then rolled up to a composite for the performance year, or if it is in fact a 3-month rolling average.

II. CMS should address community concerns about the process used to develop ESRD measures

In addition, we remain concerned about the process used to develop these measures both as participants and observers of the TEP process. First, concerns remains 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 endorse proposed measures, as opposed to an open process for responding to comments and recommendations of TEP members. Third, the process results did not always correspond with the discussions many of the TEP members understood to have occurred, leading to measures that were inconsistent with the direction the TEP suggested. For example, members on the readmissions TEP did not view the discussion as final, but rather very preliminary. Despite the need for additional discussions and refinement of the measure, the TEP was never reconvened. The process was rushed and did not allow for adequate evaluation, questioning, and refinement of the proposal. 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;
- 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 that are also shared with TEP members;
- Provide TEP members all measure comments received through this process for discussion on work group calls and permit non-TEP members to participate 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 Quality Incentive Program (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.

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.

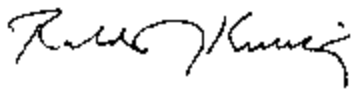
III. Conclusion

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 or problems identified during our review. 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 the Kidney Care Quality Alliance 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 and assist in refining these proposed measures. 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

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
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
Centers for Dialysis Care
DaVita Healthcare Partners, Inc.
Dialysis Patient Citizens
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 Ventures Management, LLC
Sanofi
Satellite Healthcare
Takeda Pharmaceuticals U.S.A (TPUSA)
U.S. Renal Care