April 30, 2013

Patrick Conway, M.D.
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,

The Renal Physicians Association (RPA) appreciates the opportunity to submit comments on the 30-Day Hospital Readmission Measure and Anemia Management Measures for ESRD Population. RPA is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with renal disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with renal disease.

RPA’s comments on the individual measures are included below.

- **Anemia of chronic kidney disease: Patient informed consent for ESA treatment**
  While patient informed consent for ESA treatment is an important necessity, RPA does not believe that it is a quality measure; rather, it indicates compliance with a regulatory requirement. Further, there is no evidence that it improves patient centered outcomes.

- **Anemia of chronic kidney disease: Dialysis facility ESA management to avoid transfusion**
  RPA finds this measure to be too imprecisely worded and is not sufficiently validated to assure that the factors being measured are fully appropriate. The threshold doses for EPO and Aranesp appear to be arbitrary rather than evidence-based.

- **Anemia of chronic kidney disease: Dialysis facility standardized transfusion ratio**
  RPA supports the concept behind this measure but believes it requires much more rigorous validation before it can be used as a quality measure, as there are no clear guidelines or basis of evidence to support when patients should be transfused in this population. RPA is concerned about facilities being held responsible for transfusions provided by practitioners outside of the facility. RPA believes the process under the physician’s control to avoid transfusion is maintenance of Hgb > 10g/dL.

- **Anemia of chronic kidney disease: Hgb > 12 g/dL**
  RPA supports this measure as it is aligned with an existing AMA PCPI measure that is NQF endorsed (NQF #1666).
• **Anemia of chronic kidney disease: Hgb< 10 g/dL**
  RPA believes this is an important reporting measure for transfusion avoidance and improved quality of life. A series of studies have demonstrated that treatment of anemia with erythropoietic stimulating agents to Hgb> 10 g/dL in patients with CKD reduces symptoms and in many studies led to demonstrable improvement in quality of life. A similar physician-level Hgb< 10 g/dL measure for the pediatric patient population has been endorsed by NQF (NQF #1667); the matching adult patient population physician-level measure developed by AMA PCPI and RPA was not endorsed by NQF. However, RPA understands that the hemoglobin less than 10 g/dL measures may not be an appropriate payment measure at the current time, due to the evolving understanding of the risks associated with ESA use which have culminated in label change for incorporating a Black Box Warning that make it difficult to rely upon historic data to evaluate the quality performance of dialysis facilities and providers. At the same time, as soon as an appropriate, clinically relevant hemoglobin measure is available, RPA would support inclusion of such a measure for payment.

• **Standardized 30-day readmission ratio for dialysis facilities**
  The RPA does not believe that this measure has been sufficiently validated and tested. Further, we believe the following questions related to the measure remain unanswered: 1) To what extent is variation in re-hospitalization rate attributable to other quality metrics in the dialysis facility? 2) Are the proposed case-mix adjustments reliable? 3) What are the risks of unanticipated consequences - will such a measure result in failure to re-hospitalize patients where it is appropriate? RPA is aware that during the discussions of the TEP meeting there was a strong argument that the responsibility for re-hospitalization was a shared responsibility among the discharging hospital, the dialysis facility and the nephrologist/nephrologygroup - however adjustment for this last portion was removed from the measure. Further, the concept of shared accountability between hospitals and dialysis facilities has not been formally established and there is no definitive nor mandatory financial linkage at the present time between or among these providers. Moreover, the quality of care rendered by the hospital prior to discharge is out of the control of the dialysis unit. This measure appears to be heavily, and somewhat unpredictably, influenced by the quality of the care rendered during the patient’s hospitalization and by the quality of the hospital’s discharge planning processes and procedures.

  RPA believes that this measure requires robust validation and testing to assure that it is appropriately designed, that the complex model for calculation is appropriate and that the values for the 30-day readmission ratio pass basic validation as reflecting dialysis facility quality.

As always, the RPA appreciates the scope of CMS’ efforts in the area of quality improvement, and we look forward to future collaboration with the Agency whenever possible. Questions regarding this communication should be directed to RPA’s Project Manager, Amy Beckrich at 301-468-3515, or by email at abeckrich@renalmd.org.

Sincerely,

Robert Kossmann, M.D.

President