August 30, 2011

Donald M. Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1577
P.O. Box 8010
Baltimore, MD 21244-8010

Subject: CMS-1577-P: Medicare Program; Changes to End Stage Renal Disease Prospective Payment System for CY 2012 and Quality Incentive Program for PY 2013 and 2014

Dear Dr. Berwick:

The American Nephrology Nurses’ Association (ANNA) is pleased to comment on the proposed rule CMS-1577-P: Medicare Program; Changes to End Stage Renal Disease (ESRD) Prospective Payment System (PPS) for CY 2012 and Quality Incentive Program (QIP) for PY 2013 and 2014 issued by the Centers for Medicare and Medicaid Services (CMS) and published in the Federal Register on July 8, 2011.

The American Nephrology Nurses' Association (ANNA) is an organization of over 12,000 registered professional nurses who specialize in the care of individuals with kidney disease. The majority of the Association’s membership works in outpatient dialysis facilities. ANNA develops and updates standards of clinical practice, educates practitioners, stimulates and supports research, disseminates new ideas, promotes interdisciplinary communication and cooperation, and monitors and addresses issues affecting the practice of nephrology nursing.

ANNA worked with the renal community to support the passage of the Medicare Improvements for Patients and Providers Act of 2008 and the changes the law provided within the Medicare ESRD program. Additionally, ANNA has provided CMS with information and guidance regarding the implementation of the regulations for the ESRD PPS and QIP. Nephrology nurses working in dialysis settings provide direct care to and spend more time with individuals on dialysis than any other group of healthcare professionals. Therefore, we are uniquely qualified to provide a perspective on the impact of any ESRD regulations on patients. While ANNA strongly supports any effort to improve quality care in dialysis settings, we have strong concerns regarding the changes proposed by CMS to modify the quality measures in the QIP.
Comments on the Proposed Rule

ANNA’s primary concern is that the proposed changes to the QIP may result in unintended consequences for patients undergoing dialysis and place an undue administrative burden upon nephrology nurses. Nurse staffing in outpatient dialysis settings is at a historic low as a result of health economic issues and the nursing shortage. Time spent by the registered nurse in the dialysis setting is best spent with a patient, providing education, counseling, and care. ANNA urges CMS to consider these facts in the review of our comments regarding proposed rule CMS-1577-P.

Retirement of Anemia Management Measure of Hemoglobin Below 10 g/dL

CMS is proposing in PY 2013 to retire the anemia management measure that monitors the percentage of patients with a hemoglobin level below 10 g/dL while maintaining the upper level hemoglobin measure of 12 g/dL. The proposed rule identifies medical evidence and a recent announcement by the Food and Drug Administration (FDA) revising their dosing guidelines for the use of erythropoietin-stimulating agents (ESAs) used in treating anemia in Chronic Kidney Disease (CKD) patients as the reason for retiring the hemoglobin less than 10 g/dL measure. While ANNA understands that having a lower hemoglobin level for payment in the QIP may not be appropriate for 2013 because of these recent changes, we are concerned about undertreatment of anemia and the resulting risks to dialysis patients.

The elimination of the hemoglobin level below 10 g/dL quality measure may result in lower hemoglobin values of dialysis patients with a resulting increase in patient symptoms of weakness, fatigue, and general decline in overall sense of well being; a decline of patients working or in school; more frequent hospitalizations or an increase in the number of days spent in the hospital each year, as well as longer recovery time post-hospitalization. It may also negatively impact a patient’s ability to choose a more palatable and meaningful choice of modality, such as home therapy, due to lack of energy, a decline in cognitive function, and weakness.

In addition, data suggest an association between hemoglobin less that 10g/dL and increased blood transfusions, further compromising patients awaiting kidney transplant by making organ matching more difficult. The elimination of this measure may place limits on certain patients’ ability to qualify as transplant candidates. It is well known that blood transfusions can cause the formation of antibodies that will compromise the transplant outcome. Further, frequent blood transfusions may suppress the erythropoiesis process, causing the patient to become transfusion dependent.

Because of patient safety and wellbeing issues, ANNA supports continued monitoring and reporting of hemoglobin less than 10 g/dL, preferably in the QIP, if feasible, as well as the reinstitution of an appropriate hemoglobin measure for undertreatment of anemia in the QIP for payment as soon as possible.
Dialysis Adequacy Using the Kt/V Formula in PY 2014

Currently there are several different calculations to determine dialysis adequacy. ANNA and the renal community have previously supported the use of a standardized Kt/V formula instead of the Urea Reduction Ratio (URR). ANNA was encouraged to see that CMS has recognized that the Kt/V is a more adequate measurement of dialysis adequacy, however ANNA continues to support standardized measurement and the application of a single formula. Additionally, we support a separate standardized formula specifically for more frequent dialysis therapy; e.g., daily dialysis.

Vascular Access Types

ANNA has previously endorsed and continues to endorse the mission of the Fistula First Breakthrough Initiative (FFBI) “to increase the likelihood that every eligible patient will receive the most optimal form of vascular access for him/her—in the majority of cases, an arteriovenous fistula.” We interpret this to mean not “fistula only,” but fistula first, remembering that the first rule of medical ethics is “do no harm.” We see the collection of arteriovenous fistula prevalence data along with graft and catheter prevalence as appropriate but that measures that impact reimbursement should be confined to “catheter > 90 days”. The Kidney Disease Outcomes Quality Initiative (KDOQI) has long advocated a goal of < 10% and through FFBI prevalence data (overall 8.3%, 6/2011) it is clear that this is a reasonable goal. It is also appropriate to collect “catheter only” data and the reasons for that statistic to help understand the high incident catheter rate and to formulate appropriate solutions including prevention as in “catheter never”. However, dialysis facilities cannot be held responsible for incident catheter rates.

We believe that an emphasis on decreasing long-term catheter prevalence will encourage thoughtful consideration of alternative access such as graft placement or peritoneal dialysis in those patients that are at high risk for fistula maturation failure. Recent literature provides evidence to support such an approach in order to decrease access-related morbidity and mortality. The conclusion drawn from a study of some 80,000 patients published in *Am J Kidney Dis* 2009 was that “catheters have the worst associated mortality risk. Changing from a catheter to a fistula or graft is associated with significantly improved survival. The risk for grafts approached that of fistulas, providing an alternative to prolonged catheter exposure and potentially less hazardous ‘bridge’ toward a fistula.” Additional evidence has accrued which has resulted in a tool that predicts “failure to mature” based on age, race, and cardiac pathology (Lok et al, 2006). ANNA believes that a demonstration project utilizing such a tool could provide the evidence for further guidelines in formulating a patient-centered vascular access algorithm.

ANNA appreciates that, with this measure, CMS continues to provide the flexibility to the interdisciplinary team that is necessary in identifying the optimal type of vascular access for the individual patient.

Vascular Access Infections

ANNA recognizes that CMS is trying to simplify data collection by using only the very broad category of hemodialysis access-related bacteremias. We trust that clarification will be included
for this defined measure such as “positive blood cultures in the absence of overt non-access infection or in the presence of overt access infection” to make this measure concrete. We are concerned that an infected non-access wound or a urinary tract infection resulting in positive blood cultures could be included in such a measure. We agree that it is an important measure for the increased safety of our patients.

**Ratio of Hospitalization Rates**

ANNA urges CMS to provide more details on the proposed structure of the ratio of hospitalization rates among dialysis clinic patients. While CMS contends that 90% of hospitalizations are related to ESRD, ANNA is concerned that dialysis facilities will be held responsible for conditions that are not managed nor offset by dialysis treatments. Hospitalization rates do not measure the care provided by the dialysis units, e.g. diabetic wounds, cardiac complications, and interventions. It is agreed that we must continue to monitor, report and build standardized hospitalization rates (SHR) into our Quality Assessment and Performance Improvement (QAPI) programs. However, it is not appropriate to hold us financially accountable for hospitalizations that are unpreventable through dialysis treatment.

Our concern is also related to the unintended consequence of dialysis providers accepting only those patients with minimal comorbidities; e.g. catheters, fragile elderly, previous hospitalizations, et cetera. Complex patients with multiple comorbid conditions would be very difficult to place in an outpatient dialysis unit placing a significant burden on the hospital system.

**Reports on Dialysis Infection Rates to CDC**

The proposed measure of reporting dialysis infection events to the Centers for Disease Control and Prevention (CDC) may impose a severe administrative data burden upon nephrology nurses. ANNA urges CMS to provide more specific guidance regarding which infections are required to be reported as well as the frequency of the reports.

**Administration of Patient Experience of Care Surveys**

ANNA supports CMS’ intention to use a universal tool but we urge CMS to use a tool that has been validated in the outpatient dialysis setting. We recommend that the renal community have an opportunity to review and provide feedback on such a tool before it is used for quality incentive purposes. Our research of the Consumer Assessment of Healthcare Providers and Systems (CAPHS) yielded information from 2003-2005. Dialysis facilities have changed significantly in the past six to eight years. The implementation process is always of concern, as we do not want to further burden the registered nurse with additional paperwork and documentation.

**Monitoring of Patient Abnormalities in Phosphorus and Calcium Levels**

ANNA understands the need to monitor abnormalities in certain key areas such as phosphorous and calcium. However, we have concerns about CMS’ overall objectives in monitoring these items as a part of a total quality performance score. Ensuring a facility obtains levels on a monthly basis does not reflect the impact of the values on quality patient care.
In addition, the administrative and data burden this will impose on nephrology nurses limits the amount of time that should be properly spent educating, counseling, and encouraging patients regarding their diet and medications, as well as adherence strategies. ANNA requests that CMS consider the collection of this information via CrownWeb, appropriately shifting the administration and data burden.

**Future Quality Measures**

While CMS works to implement the new proposed quality measures, ANNA encourages CMS to consider quality measures that recognize the value of the nurse/patient relationship. There have been numerous empirical studies that have evaluated the importance of the role nurses play in ensuring quality healthcare. As the healthcare professional responsible for providing the majority of hands-on care for individuals with CKD on dialysis, we believe an effective QIP must take into account the impact of nephrology nursing care.

**Conclusion**

As a contributing member of Kidney Care Partners (KCP), an alliance of members of the kidney care community, ANNA endorses the comprehensive comments submitted by KCP on CMS-1577-P. However, our comments serve to express our thoughts on the proposed rule specifically on the proposed changes to the QIP program from a nursing perspective.

ANNA looks forward to continuing to work with CMS during the implementation of the proposed changes to the QIP. Please do not hesitate to contact me if ANNA can be of assistance.

Sincerely,

Dr. Rowena Elliott, PhD, RN, CNN, BC, CNE
President
American Nephrology Nurses’ Association