January 16, 2009

Centers for Medicare and Medicaid Services
Medicare Coverage of Kidney Disease Patient Education Services
Attention: Jamie Hermansen, M.P.P.
Mail Stop CI-09-06
7500 Security Blvd.
Baltimore, Maryland  21244

Re: Comments on the AHRQ Stakeholders’ Meeting Regarding Medicare Coverage of Kidney Disease Education Services

Dear Ms. Hermansen:

On behalf of the American Nephrology Nurses’ Association (ANNA), I greatly appreciated the opportunity to participate in the Agency for Healthcare Research and Quality (AHRQ) Stakeholders’ Meeting Regarding Medicare Coverage of Kidney Disease Patient Education Services held on December 16, 2008. ANNA believes that the meeting was productive and we look forward to a continued dialogue on these issues as CMS works to draft and implement the rules that will guide the new kidney disease education services.

As you may know, ANNA is a professional nursing organization of more than 12,000 registered nurses practicing in nephrology. ANNA members are intimately involved in the supervision and delivery of care to adults and children with kidney disease. ANNA members work in a variety of settings including dialysis facilities, transplant centers, Chronic Kidney Disease (CKD) clinics, acute care, ambulatory clinics, and long-term care.

ANNA played a prominent role in advocating for the dialysis provisions that were part of the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275); specifically, we supported the patient education provisions in Section 152(b).

I am pleased to have the opportunity to provide comments on the six questions proposed by CMS that served as the framework for the stakeholders’ meeting. The following responses include my written and oral comments to the questions, as well as some additional feedback.
What are the accepted clinical criteria (or standards of practice) for diagnosing someone with Stage IV CKD and determining that the patient will need to start renal replacement therapy?

- The National Kidney Foundation’s Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines (part 10, appendix 3) review the different methods to obtain a Glomerular Filtration Rate (GFR) and stage a patient’s CKD. While obtaining 24 hour urine samples, or using the Cockroft-Gault formula was fairly routine eight years ago when these guidelines were written, the clinical practice settings now use the Modification of Diet in Renal Disease (MDRD) formula to quickly evaluate and stage a person’s GFR.

- The MDRD formula is preferable because CKD patients’ renal functions change due to many variables. Going through the process of obtaining 24 hour urine sample on a patient who, hours or days later, may have a different creatinine level is not clinically worthwhile or financially sound. While the MDRD formula is not perfect, it does provide a close approximation for use in most clinical situations. Based on the current KDOQI guidelines, a person reaches Stage IV CKD when their GFR drops below thirty. Nurses must be mindful that this may fluctuate (improve or worsen) as their condition changes, especially if the readings were taken during a time when a patient was clinically unstable and therefore had an acute component to their kidney failure.

- The decision to start Renal Replacement Therapy (RRT) is often subjective. Nephrology nurses are taught that End Stage Renal Disease (ESRD) is when a person’s GFR is less than 15 (for DM) or less than 10 (for non-DM); however, in reality it is how a person feels that is more important than the GFR number. Certain objective factors can influence this if they are refractory to standard medical therapies, such as hyperkalemia, severe metabolic acidosis, fluid overload, certain toxins, etc. In general, the majority of patients start RRT when they have uremic symptoms. The guidelines that are widely accepted are the NKF-K/DOQI CKD Clinical Practice Guidelines.

What are the different modalities of education appropriate for kidney disease patient education?

ANNA recognizes a variety of modalities of education appropriate for kidney disease education. The primary modalities include the following:

- One-on-one meetings
- Group education classes
- Self-paced learning modules
- Patient support groups

Use of patient hand-out and patient-focused web sites are excellent tools to use along with the above listed modalities.

- Patient Handouts: These allow patients to take materials home and read them at their own leisure, then return to the clinical site with any questions.

- Patient-Focused Web Sites: These websites, previewed by clinical staff, can be used by those patients who like to explore the internet and obtain information on their own.
Patient-focused web sites have been helpful and safe, while providing accurate information. After reviewing online materials, patients are encouraged to bring back questions for review.

No matter which combination of modalities of education are used, ANNA feels it is important to make the educational sessions culturally appropriate, and personalized.

**What is the recommended frequency and duration for these education services?**

When considering the frequency and duration of the education sessions, several factors need to be considered. Some of these factors include, but are not limited to, the following:

- Acuity of patient’s condition
- Readiness to learn
- Current knowledge level
- Educational level
- Number of patients attending sessions
- Learning style and other medical conditions that may affect learning (e.g., sight, hearing, etc.)
- Other patient circumstances such as travel time and job responsibilities

Other important issues to consider are the patient’s attention span and type of teaching methodology used by the educator. A person’s attention span can be affected by their physical and mental condition. An hour education session may seem optimal but the attention span of a healthy individual is usually not sixty minutes. Thirty minute sessions or a session not longer than 45 minutes may be more realistic. The type of teaching methodology used by the educator (modules, group classes, etc.) can impact the duration of the education session. Additionally, the frequency of the sessions should depend on the readiness of the patient, but should have a date for completion.

**What factors in existing education programs have led to the best patient outcomes?**

ANNA strongly believes that the collaboration between the various disciplines on kidney disease education can provide for the best patient outcomes. Also, we have found that group medical appointments, which provide for interactions with others facing the same outcome, can be beneficial. Other existing education programs that ANNA has found to provide for positive patient outcomes include the following:

- Repetitive information
- Providing education in various formats
- Education at the appropriate reading level
- Patient and family input on their learning needs and goals
- Including patient/family in the planning process (when learners have a voice in the learning process, they tend to assume more responsibility)
What are the existing chronic kidney disease education resources that are publicly available?

- Renal Physicians Association Toolkit
- Fresenius Medical Care TOPS Program
- National Kidney Disease Education Program
- Partners in Education Program, National Kidney Foundation and Abbott Laboratories
- Kidney Education and You, Davita, Inc.
- People Like Us, National Kidney Foundation
- American Association of Kidney Patients
- National Kidney & Urologic Diseases Information Clearinghouse
- The Nephron Information Center: Food Values
- The ESRD Networks
- Keeping Kidney Patients Safe: kidneypatientsafety.org
- Partnership for Prescription Assistance
- National Kidney Foundation
- Renal Support Network
- Renalinfo (Baxter)
- Kidney School

Are there organizations in existence that certify the content of the education services which are currently available to the public?

We are not aware of any in existence. It is the opinion of ANNA that if education is developed it must be evidence based.

ANNA greatly appreciates the willingness of CMS to work collaboratively with the kidney community during this rulemaking process. We look forward to additional opportunities to provide comments and feedback on the implementation of these important new services offered under the Medicare program.

Sincerely,

[Signature]

Sue Cary RN, MN, APRN, CNN
ANNA President