

**AHRQ Stakeholders' Meeting Regarding Medicare Coverage of Kidney Disease  
Patient Education Services**

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**Executive Summary**

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**Tuesday,  
December 16, 2008**

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The meeting convened at 1:00 p.m. in the AHRQ Conference Center at 540 Gaither Road, Rockville, Maryland.

**Participants:**

Neil R. Powe, M.D., M.P.H., Johns Hopkins University Welch Center  
Kim Marie Wittenberg, M.A., AHRQ  
Paul W. Eggers, Ph.D., National Institute of Diabetes and Digestive and Kidney Diseases  
(NIDDK)  
Karen Basinger, American Dietetic Association Renal Practice Group  
Sue Cary, American Nephrology Nurses' Association (ANNA)  
Dolph Chianchiano, J.D., M.P.A., National Kidney Foundation (NKF)  
Ann Compton, Virginia Commonwealth University (VCU), Division of Nephrology  
Jamie Hermansen, M.P.P., CMS  
Thomas Hostetter, M.D., American Society of Nephrology (ASN)  
Alice McCall, American Association of Kidney Patients (AAKP)  
Jennifer St. Clair Russell, American Kidney Fund (AKF)  
Marcel Salive, M.D., M.P.H., CMS  
Tonya Salstrom, Dialysis Patient Citizens  
Dale Singer, Renal Physicians Association (RPA)  
Beth Witten, Medical Education Institute, Missouri Kidney Program

## Opening Remarks

Ms. Wittenberg convened the meeting at 1:03 p.m. and welcomed everyone. The purpose of the meeting is to solicit feedback on Section 152(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), which provides coverage for education services for patients with stage IV chronic kidney disease (CKD). CMS commissioned AHRQ as an outside agency to convene the meeting. Ms. Wittenberg introduced the participants seated at the head table, Dr. Marcel Salive, Jamie Hermansen, Dr. Paul Eggers, and Dr. Neil Powe.

Dr. Powe discussed the provisions in Section 152. Kidney disease education services are defined as education services furnished to an individual with stage IV CKD who, according to accepted clinical guidelines identified by the Secretary, would require dialysis or a kidney transplant. Stage IV applies to individuals with glomerular filtration rate (GFR) of 15 to 29, and it is estimated from NHANES data that there are about 700,000 individuals in the United States with stage IV disease. The services are intended to provide comprehensive information regarding management of comorbidities, including for purposes of delaying the need for dialysis, the prevention of uremic complications, and each option for renal replacement therapy. They should be designed to ensure the individual can actively participate in the choice of therapy and should be tailored to meet the individual patient's needs. They should be furnished by a qualified person upon the referral of a physician managing the kidney condition. No individual should be furnished more than six sessions of education services. Congress intended for these provisions to be implemented by January 1, 2010.

Dr. Eggers discussed the magnitude of the problem of kidney disease. There has been a very rapid increase in the incidence of disease, and those over 65 now account for half of all new patients. Blacks are four times as likely as whites to have end-stage renal disease (ESRD); Native Americans twice; and Asian Americans 40 percent. We are just beginning to become aware of the effect of acute kidney injury on kidney disease; 30 to 50 percent of all cases of ESRD may arise with no warning. In terms of vascular access, 80 percent of people on their first routine dialysis treatment get access through a catheter, 14 percent with a fistula, and very few with a graft. About 60 percent of people that go into ESRD were already under the care of a nephrologist, and 30 percent were not. For those who have been under a nephrologist's care, 22 percent have a functioning fistula as opposed to 14 percent otherwise. Sixty-five percent start with a catheter with no other access yet being planned. Most people are finding out about transplantation options, but it is highest for the youngest age groups at 71 percent.

In summary, many ESRD patients are old and frail. Many ESRD patients are unknown until ESRD, which will have an impact on the effectiveness of any education program. Pre-ESRD care is low for many ESRD patients. Only about half of ESRD patients have Medicare coverage prior to ESRD.

Dr. Powe discussed the conduct of the meeting.

**Question 1: 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 (RRT)?**

(a) Preliminary Feedback

- According to the National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines, a GFR less than 30 for over three months. However, this has not been validated in early kidney disease. New derivations of the formula will provide more accuracy, as may combining serum cystatin C with estimated GFR (eGFR). To decrease variability between creatinine methodologies, it is best to use a lab that traces its serum creatinine technique to IDS, and the MDRD study equation has been slightly modified to account for such labs.
- The decision to start RRT is often more subjective than objective and is based on how the patient feels. In general patients start RRT when they have uremic symptoms.
- The accepted clinical criteria are those found in the NKF KDOQI Clinical Practice Guidelines: eGFR between 15 and 29. Those with Stage V CKD who are not yet on dialysis should also be eligible for this benefit.
- Two consecutive measures of GFR between 15 and 29 within a 3 month period

(b) Feedback Provided at Meeting

Sue Cary, ANNA, said they went to the KDOQI guidelines because they provide evidence-based guidelines for all stages of CKD. One limitation of the GFR cut-off is that it was selected based on limited data with respect to the relationship between complications and level of GFR, so we need to stay mindful of patients near the borderline. Regarding starting RRT, factors include how the patient feels, uremic symptoms, patient preferences, things like hyperkalemia and anemia that become refractory to medical therapies as the patient nears end stage, and poor nutritional status. Clinical criteria for when to start RRT also depend on the modality of treatment chosen.

Dale Singer, RPA, said that RPA had published an evidence-based clinical practice guideline entitled Appropriate Patient Preparation for Renal Replacement Therapy. Advanced CKD, those with CKD Stages IV and V who are not on RRT, are those with GFR of less than or equal to 30 when kidney function is at a high risk of progression. RRT usually does not begin until Stage V when GFR is less than or equal to 15, but some patients with uremic symptoms, nutritional deficiencies, or other compelling factors may require initiating dialysis in Stage IV. Some preemptive kidney transplants are performed in late Stage IV to early Stage V when clinical circumstances suggest it and appropriate donors are identified.

Thomas Hostetter, M.D., ASN, noted that many of these patients are elderly and will die before reaching ESRD and others will drop in later, so we will be teaching many of them things they will never need to know; on the other hand, there are other messages to get to these patients other than what will happen when they reach end-stage.

Beth Witten, Missouri Kidney Program and Medical Education Institute, said one important part is educating as many people as we can to prevent kidney failure, which is very expensive to Medicare. She cautioned against overly narrowing the focus of who should receive the education given the value in preventing kidney failure.

Dick Rettig, RAND Health, said the implication of Dr. Hostetter's and Ms. Witten's comments was that the statutory limitation of this education on Stage IV is

inappropriate. Dr. Hostetter agreed and said benefits would accrue if we could slow progression at even earlier stages.

Dolph Chianchiano, NKF, said it is unfortunate the statute does not include patients in Stage V CKD not yet on dialysis.

Dr. Powe asked whether the content of the education would vary by the stage of disease. Dr. Hostetter said in Stage III it would be more worthwhile to discuss slowing disease progression rather than options for RRT.

Dr. Eggers noted that the staging criteria require microalbuminuria in Stages I and II but not III, so many patients end up in Stage III largely because of age.

Eileen Newman, National Kidney Disease Education Program (NKDEP), said that education is a continuous process that begins early.

Ann Compton, VCU, said there is the opportunity to really slow progression in Stage III, especially in patients that are young with diabetes and hypertension.

## **Question 2: What are the different modalities of education appropriate for kidney disease patient education?**

### (a) Preliminary Feedback

- Face-to-face one-on-one and group classes and electronic/interactive have all been effective.
- Handouts, patient-focused websites, one-on-one, group classes, self-paced learning modules, patient support groups, and site visits to dialysis units
- Face-to-face education among peers is the preferred modality; telemedicine contact is an acceptable form of face-to-face education. There should be flexibility in the balance between group and one-on-one sessions. Classes should be between 25 and 30 participants, including family members/caregivers. There should be take-home materials to reinforce educational messages.
- Group education face-to-face or by internet plus one-on-one sessions to answer individual questions and address individual lab values and comorbidities in a confidential way. There should be a variety of materials to address varied learning styles.
- Education should be delivered by multidisciplinary teams to mirror how care will be delivered once the patient is placed on RRT.

### (b) Feedback Provided at Meeting

Jennifer St. Clair Russell, AKF, said there can be multiple goals for patient education, including improving outcomes, increasing patient efficacy, providing hope, increasing patient involvement in decision making, and increasing patient-provider communication. There should be a combination of face-to-face small group sessions along with one-on-one. It should be developed using adult learning principles. Sessions should last 45 minutes to an hour and focus on three to five key points. Group sessions should be limited to 10 to 12 patients and include family and caregivers. In terms of multimedia, things like teleconferencing and videos should be incorporated, but internet and computer-based learning should be limited due to accessibility issues.

Tonya Salstrom, Dialysis Patient Citizens, agreed with the points made by Ms. Russell and talked about the importance of empowering patients to take better care of

themselves by presenting information in a way that the population can understand. There can be a combination of written materials, internet education, face-to-face, and videos; the important thing is that the education needs to be personalized. Regardless of the method, focus should be on comprehension, understanding, and reinforcement. It is important for a family member to attend the sessions with the patient.

Ms. Cary, ANNA, highlighted the importance of personalized, individualized, and culturally appropriate.

Jenny Kitsen, ESRD Network of New England, noted there are a disproportionate number of geriatric patients for whom it is critical to educate the patient's significant other or family support system.

Ms. Compton, VCU, said we should not assume there is any relationship between education level and health literacy.

Dr. Powe asked what size a small group should be. Ms. Salstrom said fewer than 20 people and suggested community health centers as a good place to hold the sessions

Eileen Newman, NKDEP, said the legislation should include nurse practitioners, registered dietitians, social workers, etc. as providers of the education services.

Ms. Russell said the education should be multidisciplinary, but just because someone is a content expert does not make them an educator.

Karen Basinger, Renal Practice Group, American Dietetic Association, said her classes have five patients plus family members and caregivers. We also must be culturally sensitive to the learners and ensure they can understand the educator. She may take ten sessions with her elderly patients.

Ms. Salstrom agreed that the number of sessions is problematic and suggested, particularly for those in rural areas, that there could be a combination of face-to-face sessions with other formats since transportation can be such an issue.

Deborah Williams, Baxter Healthcare, said the benefit is constructed under the physician fee schedule as a clinical service but hoped that there would still be community education that could also refer people to their nephrologist for more intensive sessions.

Mr. Rettig, RAND, wondered about the modality of using beauty parlors and hair salons to get information out to the community.

Dr. Hostetter, ASN, urged that there be focus in the education program on delaying dialysis, at least for a significant period of time, as well as on early transplantation, which may not be in the interest of many of the people who will be delivering these education services. He asked for comments on using dialysis units as sites for providing these services. Ms. Russell agreed with the point about using health centers and other places out in the community. She thought there could be value in visiting a dialysis unit but thought holding all the sessions there could sway patients towards a particular treatment. Ms. Salstrom agreed. She also discussed the benefit of a Stage IV patient talking with a dialysis patient about how he or she ended up on dialysis.

### **Question 3: What is the recommended frequency and duration for these education services?**

(a) Preliminary Feedback

- Stage IV patients should receive five sessions; education for Stage V patients should focus on modality selection and have differentiated sessions depending on the patient's choice.
- Weekly for a minimum of one hour per session
- NKF's People Like Us, Live! program has six one hour in-class presentations. Patients should have a choice of various schedules so it will be more likely they will participate. Each session should consist of standardized elements so a patient can pick up where he/she left out in the case of missing a session or moving to another location.
- Initial CKD education should be limited to ten hours plus an additional two annually. There should be six one hour group sessions followed by individual sessions of at least one hour each with a physician, nurse, dietitian, and social worker
- 45-60 minute duration, once weekly, but patient schedule and attention span must be considered.
- Frequency and duration of education services depend on the severity of disease and presence of comorbid factors and complications.

(b) Feedback Provided at Meeting

Ms. Compton said the patient education program at VCU happens to be six sessions that meet weekly for an hour. What works for the patients is important. Convenience to another appointment may be helpful. The ANNA core curriculum says that CKD patients have short attention spans, so 10 to 15 minute sessions are about all they can handle. Patients may have depressed mentation and a lot on their minds. Presenting points early and repetitively is important. Sessions should take place in a non-threatening environment where the patients feel comfortable. We must allow adequate time to answer questions and concerns. The VCU program has a consistent schedule, and patients can attend classes in any order and as many times as they need. Significant others are welcome. Incentives may be important, such as getting to see the doctor first, cookies, or juice. A multidisciplinary approach is important.

Ms. Witten discussed the Missouri Kidney Program's Patient Education Program. There are six one hour classes. They are highly interactive and multidisciplinary. For the classes on treatment options, there are patient presenters. In addition to the six sessions, there should also be individual counseling with the various modalities so patients' unique questions can be answered as well as a two hour annual session so patients can brush up on anything they missed or may have forgotten. Because some people had trouble attending evening sessions, there are classes on Saturdays and Sundays so patients and their family members are more likely to attend. In each class, there is a 15 minute break in between each of the topics so patients can talk to each other and the presenters. There is an evaluation including a pre and post-test to see whether the classes are improving knowledge. Patients rate the program highly, and their knowledge increases significantly.

Ms. Salstrom asked when the Missouri Kidney Program's post-test is administered and whether there is additional follow-up to look at retention. Ms. Witten said the post-test is given after completion of the last session, but currently there is not additional follow-up. Research this year will look at whether patients who expressed a preference for a particular treatment modality actually ended up in that modality.

Ms. Basinger, American Dietetic Association, said there is a separate Medicare benefit for early dietary intervention for CKD. Through diet and education 50 percent of clients in her setting in five years have not progressed any further in Stage IV.

Dr. Powe asked if an hour is too long if the attention span of these patients is 10 to 15 minutes. Ms. Compton said follow-up is the only way to know. Dr. Hostetter said that according to NHANES data for people under 65 with Stage IV CKD but no history or evidence of a stroke, there is already significant cognitive impairment. He put that forward as a strong reason for having a healthy family member accompany the patient whenever possible.

Ms. Hays, University of Wisconsin, said a strength of the Missouri Kidney Program education service is flexibility in changing the timing of sessions according to what the population needs. Perhaps the main intention should be to get people interested enough to talk more with their nephrologist and to help people make an informed choice about their treatment modality to avoid the added expense to Medicare and burden to the patient of switching modalities. Hopefully the curriculum will also improve the abysmal rate of preemptive transplants.

#### **Question 4: What factors in existing education programs lead to the best patient outcomes?**

##### **(a) Preliminary Feedback**

- Patient to patient education programs have been an effective source of information. Because of high illiteracy rates, video and face-to-face education would benefit many patients.
- Early referral to the nephrologist, a multidisciplinary team, and simply making patients aware of their disease.
- Collaboration between the various disciplines, peer interactions, repetitive information provided in various formats, and using the appropriate reading level.
- Patient presenters, objectivity, presenters well versed in all aspects of every treatment modality, balanced, and comprehensive.
- Initial education by the nephrologist, the patient being an active participant, qualified practitioners, and individual as opposed to group education.
- Make information applicable to the patient, follow-up, and a multidisciplinary approach.

##### **(b) Feedback Provided at Meeting**

Mr. Chianchiano, NKF, discussed the People Like Us video series and People Like Us, Live! education program. Success is defined as how well a program helps patients cope with and manage their disease. Some components of successful education programs are:

- patient input in development of the programs
- promoting patient empowerment
- alignment with evidence-based practices
- family participation
- not driving patients to a specific treatment or provider
- that educators be well versed in all aspects of every treatment modality

- that all modalities be given equal time and attention and all their pros and cons explained
- face-to-face interaction
- peer-to-peer interaction in group sessions as well as opportunities for confidential discussion
- standardized content
- repetitive learning opportunities
- a mechanism for evaluation of patient participation and of the relationship between the education program and health outcomes

Ms. Basinger, American Dietetic Association, said one key point is including the nephrologist. The patient needs to be an active participant. Qualified practitioners must be included. Practitioners must have a renal background. The medical nutrition therapy (MNT) benefit must be better utilized. The best outcomes are derived from individual counseling along with the education. Outcomes are achieved from patient-focused, intensive interventions centering on behavior changes.

Dianne Logan, Fresenius Medical Care, recommended that the qualified person providing the education services have a nephrology background.

Ms. Salstrom said the legislation also talks about public awareness campaigns which could help educate the medical community.

Ms. Cary talked about one-stop shop clinics run by advanced practice nurses who coordinate with a dietician and others to make sure patients get the benefits of a multidisciplinary approach.

Brenda Ortiz, TMF Health Quality Institute, agreed that nephrologists or renal dieticians would be the most appropriate people to deliver this program but was concerned that in some areas there may be a shortage of those professionals. Another issue is that primary care physicians may not be aware of the programs that Medicare covers, and, even if they are, they may not know what specific programs to refer their patients to.

Dr. Powe asked if standardization is compatible with individualization. Mr. Chianchiano said the program should be standardized in terms of certain specific topics that have to be covered; the way that information is delivered should then be individualized to the needs of the particular patient.

Dr. Hostetter asked how one would evaluate the societal or economic benefit of this CMS program. Mr. Chianchiano said one obvious parameter would be delayed disease progression. Another would be the type of vascular access the patient has at initiation of dialysis. Other parameters might include whether patients remain employed or have undergone rehabilitation training, general health status, and coping.

Debra Washington, NKF, talked about the benefit of having patient volunteers talk to other patients.

Mr. Rettig, RAND, asked whether Medicare and others should reimburse, under appropriate circumstances, the estimation of GFR, particularly given that the Welcome to Medicare benefit includes referral for MNT, which requires a GFR. Dr. Hostetter said about 40 percent of labs report this but was unsure whether patients know what their values are.



Returning to the question of providers, Ms. Compton said they should meet certain criteria whether they are in nephrology or not.

**Question 5: What are the existing chronic kidney disease education resources that are publicly available? In addition to the resources, please provide information regarding the sponsorship or funding provided to produce the existing education programs.**

(a) Preliminary Feedback

- There are many brochures, articles, and websites developed by non-profit kidney organizations and dialysis providers, generally sponsored by dialysis providers and pharmaceutical companies. There are also a few live education and teleconference courses. NIH also has educational materials.
- NKF's People Like Us video series and People Like Us, Live! workshop program are among the widest utilized.
- AKF maintains a resource list available to patients by calling AKF's help line.
- Best programs come from AAKP, NKDEP, NKF, and RPA. An outstanding resource for nephrologists is NephSAP's manuals and test booklets sponsored by ASN.

(b) Feedback Provided at Meeting

Alice McCall, AAKP, said her organization has been providing education resources for patients since 1969. The educational series AAKP Kidney Beginnings includes a live seminar and electronic newsletter. AAKP MyHealth, an online personal health record, also provides education as to the meaning of patients' lab values. The AAKP Patient Plan was created with Stage IV patients in mind and allows the patient to take in information in a more controlled fashion when he or she is ready. The ESRD options portion of the education should take a conservative approach and include discussion of advance directives. AAKP materials are available directly to patients through sponsorships, but the organization is willing to discuss alternative options for distribution.

Dr. Hostetter, ASN, said there are high quality resources within the National Institutes of Health. One is NKDEP, which targets providers and those at risk for kidney disease. It primarily targets primary care physicians and other groups like laboratory professionals to improve the reporting of creatinine and in turn the accuracy of eGFR. Another resource is the National Kidney and Urologic Diseases Information Clearinghouse, also run by NIDDK in NIH. Multiple publications are available essentially free of charge. The materials available from NIDDK are scientifically reliable and unbiased and intended for both patients and providers. They are taxpayer funded resources.

Ms. Russell said AKF's help line staffed by health educators is available in English and Spanish. AKF also has a brochure series. Returning to an earlier point, she noted that simply because a piece of literature is translated does not mean it is culturally appropriate. She also highlighted the principles of health literacy and writing materials using plain language principles.

Mr. Chianchiano said NKF is part of the Kidney Care Partners Coalition, which has a workgroup charged with making recommendations to CMS on implementation of Section 152(b). The workgroup will assemble a catalog of programs that might be useful for this new education service and would be happy to provide it to CMS and AHRQ staff.

Ms. Singer, RPA, said a CKD patient management toolkit was created and is being field tested to look at patient outcomes.

Ms. Witten said Medical Education Institute also has Kidney School, an interactive web-based program, and the website Home Dialysis Central, which helps patients and professionals evaluate candidacy for home dialysis therapy.

Dave Switzer, PKD Foundation, said there are many organizations like his that provide niche information on specific types of chronic kidney disease.

Mr. Rettig, RAND, proposed awarding an annual prize for the best CKD education.

**Question 6: Are there organizations in existence that certify the content of the education services that are currently publicly available? In addition, please provide information regarding sponsorship or funding provided to these certification entities.**

(a) Preliminary Feedback

- No certification program, but there would be benefit in creating one independent of dialysis providers and pharmaceutical companies
- Certification should be discouraged because it is expensive. There is a lack of evidence that it leads to better outcomes, and organizations creating content have scientific advisory boards reviewing information before dissemination.
- Recommend against creating a body to certify kidney education.
- CKD education should follow the Diabetes Self-Management Training (DSMT) model.

(b) Feedback Provided at Meeting

Mr. Chianchiano, NKF, began by discussing legislative history. There is currently no certification body for kidney disease patient education. NKF's Kidney Learning System has an editorial board that is responsible for certifying that its educational programs are accurate, unbiased, and consistent with clinical practice guidelines of NKF and peer organizations. The board oversees development, approves and reviews content, and facilitates pilot testing. It is a multidisciplinary, multispecialty board with 71 members.

Ms. Witten, Medical Education Institute, discussed the need to certify professionals to provide education using certain minimal education and nephrology experience requirements and a standardized exam covering topics related to the CKD curriculum. The American Diabetic Association and Indian Health Service are approved accrediting organizations under the DSMT benefit. The under-utilization of that benefit should be considered when setting up the CKD education benefit. Instead of having to collect 12 months of outcomes data as with DSMT, one should only need six months before applying to be a provider of CKD education services.

Ms. Singer, RPA, voiced her opposition to certification and said providers are already certified to provide CKD care. We must think carefully about access and reimbursement.

Ms. Williams, Baxter Healthcare, discussed the provision dealing with rural hospitals. She thought it was good since there aren't many nephrologists in rural areas but was unsure how it would work.

Dr. Powe asked about the high number of patients with diabetes and CKD and wondered about having professionals certified to do both kinds of education. Ms. Witten thought it would be great but said it would have to reimburse enough to make people want to get certified. Ms. Basinger didn't think the right messages would get to the patients with joint education.

Ms. Ortiz, TMF Health Quality Institute, talked about the importance of location to whether people attend and said that many groups, such as Hispanics and African Americans, prefer group instruction to one-on-one. She also supported the comment that there needs to be an easy way to find resources in one's community.

Ms. Russell, AKF, suggested that the educators need to have at least a basic understanding of education theory.

#### **Further Discussion**

Ms. Ortiz, TMF Health Quality Institute, wondered whether, if this benefit were under Part B, there would be a copayment.

Mr. Chianchiano, NKF, asked whether a nurse practitioner or physician assistant would be allowed an office practice expense if they attempted to directly bill CMS.

**The meeting was adjourned at 4:26 p.m.**