U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

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AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

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STAKEHOLDERS' MEETING REGARDING MEDICARE COVERAGE OF KIDNEY DISEASE PATIENT EDUCATION SERVICES

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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, 540 Gaither Road, Rockville, Maryland, Neil R. Powe, M.D., M.P.H., Moderator, presiding.

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

KAREN BASINGER, American Dietetic Association Renal Practice Group

SUE CARY, American Nephrology Nurses' Association

DOLPH CHIANCHIANO, J.D., M.P.A., National Kidney Foundation

PARTICIPANTS: (cont.)

ANN COMPTON, Virginia Commonwealth University, Division of Nephrology

JAMIE HERMANSEN, M.P.P., CMS

THOMAS HOSTETTER, M.D., American Society of Nephrology

ALICE McCALL, American Association of Kidney Patients

JENNIFER ST. CLAIR RUSSELL, American Kidney Fund

MARCEL SALIVE, M.D., M.P.A., CMS

TONYA SALSTROM, Dialysis Patient Citizens

DALE SINGER, Renal Physicians Association

BETH WITTEN, Medical Education Institute, Missouri Kidney Program

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P-R-O-C-E-E-D-I-N-G-S

(1:03 p.m.)

MS. WITTENBERG: Well good afternoon, and welcome, everyone. I'm Kim Wittenberg. And welcome to the AHRQ Stakeholders' Meeting Regarding Medicare Coverage of Kidney Disease Patient Education Services.

The purpose of this meeting is to solicit feedback regarding Section 152(b) of MIPPA, Medicare Improvements for Patients and Providers Act of 2008, which provides Medicare Coverage for kidney disease patient education services for individuals with stage IV chronic kidney disease, or CKD.

And Dr. Neil Powe is going to be responding further on 152(b).

CMS commissioned AHRQ to convene this meeting, as AHRQ is an outside agency that is a science partner to CMS.

I'd like to run through abbreviated bios for the group at the head table here

today. And just so you know, in your handouts, you'll have more substantial bios for all the folks here.

Dr. Steve Phurrough was going to attend today, and unfortunately he had a conflict, and he sends his regrets for not being able to be here today.

So the first person I'm going to introduce is Dr. Marcel Salive, on your far right. He is the Director of the Division of Medical and Surgical Services at CMS, and he serves on the Board of the American College of Preventive Medicine, and the American Board of Preventive Medicine. And is a Captain in the US Public Health Service Commissioned Corps.

Next is Jamie Hermansen. She is the Health Insurance Specialist for the Division of Medical and Surgical Services within the Coverage and Analysis Group at CMS.

Next to Jamie is Dr. Paul Eggers. He is the Program Director for Kidney and Urology Epidemiology at NIDDK. He oversees

the United States Renal Data System, the Urologic Diseases in America Project, the Boston Area Community Health Study, the Frequent Hemodialysis Community Network clinical trial, the NIDDK Data Repository, and the RAND Interstitial Cystitis Epidemiology Survey, or RICE.

His research on ESRD includes epidemiological studies of mortality and morbidity among ESRD beneficiaries, transplantation studies and cost studies of dialysis and transplantation. And he has over 70 publications concerning various issues relating to the Medicare program, and ESRD in particular.

Last is Dr. Neil Powe. He is a James Fries Professor of Medicine and Distinguished University Service Professor at the Johns Hopkins University School of Medicine. And Professor of Epidemiology and Health Policy and Management at the Johns Hopkins University Bloomberg School of Public

Health.

He is the Director of the Welch Center for Prevention, Epidemiology and Clinical Research. He has extensive experience in developing and measuring outcomes in chronic kidney disease. And is currently serving as PI of a CDC sponsored project to design a surveillance system for CKD in the United States.

He serves on the National Advisory Committee for Healthcare Research and Quality, and the Board of Trustees of the American Board of Internal Medicine. He is a Fellow of the American College of Physicians, and also a member of the American Society of Clinical Investigation, the Association of American Physicians, and the Institute of Medicine.

Just some general information for this meeting, the restrooms are located directly across the hall behind us here. And one hallway back, right near the entrance, is where the snack machines and drink machines

are located. If you go down that hallway, on your left is the kitchen, and that's where those machines are.

Also there will be several opportunities throughout the meeting for comments and questions.

Please always use the mics that are here in the aisle. This meeting is being recorded, so we need you to actually use the microphones to pick up your voice for the recording. Also, please begin by introducing yourselves and stating your affiliation.

After this meeting is over, sometime early next year, we will be producing an executive summary of the meeting.

And just to end the disclaimer for the meeting, statements, opinions, and-or positions made by the moderators, speakers, and-or the public, are independent of the United States Government. They should not be construed as an official position of AHRQ, CMS, NIH, or HHS. Reference to any specific

commercial products, process, service, manufacturer, company, or trademark, does not constitute its endorsement or recommendation by the United States Government, HHS, AHRQ, and-or CMS.

Thank you very much.

Dr. Powe?

DR. POWE: Well, I want to welcome all of you to this meeting this afternoon, and thank you for being here to participate in the meeting.

When Congress creates a public law, they usually have an intent in mind for that public law. But, in fact, through the public law, they instruct our Federal Agencies to write regulations that will help implement the intent of that law.

And that's why we're here today, and want to hear from all of you in the community, to understand how this law could be implemented in an optimal fashion to in fact address the intent that Congress had for this

law.

So, what I'm going to do here is to go over the provisions that are in this law with you, in HR6331, which is the Medicare Improvement Act for Patients and Providers of 2008.

And in that public law, there actually were a number of sections that pertained to patients with kidney disease. Section 152, kidney disease education and awareness provisions, which we're going to address. And then renal dialysis provisions.

But really the focus of this meeting is really on section 152, on kidney disease education and awareness provisions. We're not going to address the provisions in the other sections today.

So let me just go through with all of you what I extracted from the law that I think the key provisions that Congress was trying to say with this law. They defined kidney disease education services as

educational services that are furnished to an individual with stage IV chronic kidney disease who, according to accepted clinical guidelines identified by the Secretary, would require dialysis or a kidney transplant.

And I want to remind you this classification, the CKD classification that we have now, includes stages I through V, and their intent really applied to this stage, stage IV, for which the prevalence of disease is about .35 percent. These are individuals who have an estimated glomerular filtration rate of 15 to 29 milliliters per minute per 1.73 meters squared.

There are estimated, through this data from NHANES that there are about 700,000 individuals in this country today who have stage IV kidney disease, a far greater number with lesser degree stages, and a few less with stage V as Dr. Eggers will talk about in a minute. But that's who these services were intended to be applied to.

So these services are supposed to be designed to provide comprehensive information regarding the management of comorbidities, including for purposes of delaying the need for dialysis, the prevention of uremic complications. And each option for renal replacement therapy, including in-center and home services as well as vascular access options and transplantation.

And Congress said the services should be designed to ensure that the individual has the opportunity to actively participate in the choice of therapy, and that they should be tailored to meet needs of the individual patient.

They also said that they should be furnished upon the referral of a physician managing the individual kidney condition by a qualified person. And by qualified person, they designated a physician or physician assistant, nurse practitioner or clinical nurse specialist, who furnishes services for

which payment can be made under the CMS fee schedule, but also by providers of services located in a rural area.

An interesting part of this is that they said that this does not include a provider of services other than those in a rural area or a renal dialysis facility.

And they said, in terms of payment that no individual should be furnished for more than six sessions of kidney disease education services. And Congress' intent was to have this implemented by January 1st of 2010, so roughly a year from now. And that's why we're here today, because what they instructed, the Secretary of the Department of Health and Human Services, to do, was to set standards for the content of information to be provided, after consulting with a variety of individuals shown on the slide.

To the extent possible the Secretary shall consult with persons or entities, other than a dialysis facility, that

has not received industry funding from a drug or biological manufacturer or dialysis facility. That's why we asked you all to fill out a disclosure form when you came in to the meeting.

So that is what really the key provisions of this law, that we're going to discuss today. But before we get into the comment period, we thought it would be useful for Dr. Eggers to show you a little bit about the magnitude of the problem of kidney disease in this country.

So I'll turn it over to Dr. Eggers.

DR. EGGERS: Thanks, Neil.

I think probably most of you are already familiar with a lot of the stuff that I'm going to show, but it's always been my feeling that it helps to give some background information just to make sure that we're all talking about the same kind of thing here.

So, I asked him, to just give them some opportunity to talk a little bit about

what we already know about this issue that we're going to talk about today.

So the first thing is something that's pretty straightforward to most of us. But it's a problem of aging and of minorities.

This is the trend in incidence from less than 20,000 people in 1980, to almost I think it's a bout 110,000 in 2006. So a very rapid increase. And as you can see, most of the increase has been in the older ages, so that those over 65 now account for half of all new patients. And those over 75 account for about a quarter of all new patients.

And it is a disease of minorities, as we well know. And so these are by age the incident rates per million, by these various racial categories here. And as you can see, Blacks are almost four times as likely as Whites to have ESRD. Native Americans twice, and Asian Americans 40 percent more likely to go onto ESRD.

Another thing that we're not

terribly informed about, but are beginning to be more aware of, is the effect of acute kidney injury on end stage renal disease. It's been sort of appreciated for a long time that the chronic part of kidney disease eventually leads to end stage renal disease. But we're just beginning to study this acute episode here.

So this is just sort of a cartoon that I put together. And we have sort of kidney function over here, GFR, on this one. And this is time, these units don't mean anything. So stage IV, obviously starts right about here. And stage V is down around here. So that would be stage V.

And this is sort of the concept I think that most people have about a smooth transition from impaired kidney function all the way down. At some point they would reach stage V and require dialysis or a transplant.

And of course you have other patients, and they would, depending on their

conditions and everything, proceed at different rates.

But what apparently happens in a lot of cases is you have people that are going along, and then boom, they all of a sudden drop on kidney function. They have an acute episode of whatever. And in terms of planning, you can see that in a lot of cases, at least it's my feeling from looking at the data and talking with nephrologists, that you know, you might start planning and do your education right around here, but the patient sort of drops.

And of course, something that's even a worse situation, is a patient that's up here, somewhere in relatively good kidney function, and has an acute episode, and ends up on end stage renal disease.

And the magnitude of these two things is really sort of unknown, but if you talk to any nephrologist, they might estimate anywhere from 30 to 50 percent of all cases of

ESRD sort of come out of the blue. They're just not known, and are going to be very difficult to target for any kind of educational purpose.

And this is just showing that in the year 2004, the number of people who went to ESRD, who had at least one hospitalization for acute kidney injury in the two years prior the ESRD, was upwards around 30 percent or so.

So what do we know already about patient preparation? The new, relatively new, CMS 2728 form that tells us about the patient population, in terms of vascular access, 80 percent of the people, their first routine dialysis, they're getting the access through a catheter, okay, 14 percent start with a fistula, and as you can see, very few start with a graft.

Secondly, how many people that go into ESRD were actually under the care of a nephrologist prior to going on to ESRD? Well it's about 60 percent. Thirty percent, they

were not. Additional 10 percent, unknown, I think it's probably reasonable to assume that that's probably a none.

And then within that 60 percent, this is the length of time that they've been under the care of a nephrologist. So, again, within six months, it's going to be a little bit difficult to figure out how long those people have been really effectively identified. As you can see, maybe a quarter have been under the care a year or more. So that is a major issue.

Now, another thing, which isn't terribly hopeful at this point in time anywhere, is that if a person has been under the care of a nephrologist, rather than 14 percent of them having a functioning fistula, it's 22 percent. So that's in one sense a lot more, but it isn't real great.

So if they aren’t under the care of a nephrologist there's almost no chance that they start off with a fistula. And if they've

been under the care of a nephrologist for as much as a year, there's still only 28 percent of them start with a fistula.

But of course it's more complicated than that. So if they do have a catheter, at least is there a maturing fistula? Because you can well imagine a situation in which they put a catheter in, and are waiting for it to mature. It may take six, eight weeks, maybe three months, and they need to go on dialysis right away, so you put a catheter in there. Is the fistula maturing?

And so it's about 20 percent. It doesn't vary much by demographics, okay. No one group could you say is really, you know, wonderfully prepared at the time of ESRD.

And then the, sort of the most optimistic way of looking at it is, do they have a fistula or a graft, or do they have a maturing fistula or a graft? Okay, so again, that's only about 35 percent there. So, another way of thinking about that is 65

percent start with a catheter with no other access yet being planned.

Although, what about transplantation options? Most people are getting their, or finding out about transplant. And again, it's highest for the youngest age groups, as you can see it's, what, 71 percent there. And then it decreases with age, and some variation by gender and race.

And then finally, I think, the reason patient was not informed of transplant options. We haven't looked at this in great detail yet, but some were declared medically unfit. Not much detail about that.

A big percent were not assessed. So it's a sort of a strange answer, you know, why didn't you assess them? And the answer is, they weren't assessed. You have a sort of self-evident one might say there.

And then a bunch of these that were deemed sort of too old for a transplant. And

98 percent of these, 98, 99, percent of these, are over the age of 65.

One thing other to consider is, what about insurance coverage at the time of ESRD? Again, 53 percent are Medicare entitled, so you have all of the aged there, as well as some disabled people already. So in terms of Medicare coverage, this is the group that you look at there.

And then a bunch of them are under an employee group health plan, or Medicaid, or some other kind of thing there. And then a small percentage there are uninsured.

So, just to summarize there, in terms of what we're dealing with, many ESRD patients are old and frail.

Many ESRD patients are unknown until ESRD. So the effectiveness of any sort of education program is going to be greatly affected by this problem right here, which of course we're working in other areas to try to figure out.

Pre-ESRD care is low for many ESRD patients. So the bright way of looking at that is there are opportunities for improvement. All right?

And then, only about one half of ESRD patients have Medicare coverage prior to ESRD.

Thank you.

DR. POWE: Thank you, Paul. That was a wonderful, wonderful background.

And so, what I'm going to do next is to tell you a little bit about how we're going to conduct this session this afternoon. This is really a session made to hear from you.

We solicited all of you about six questions regarding this public law. And you might say, well why were those six questions that were asked? And that's because they were prime interests to AHRQ and CMS as information that they need, they determined that they need, in order to implement regulation for

this.

So, what we're going to do, we're going to have two sessions here. We're going to have, the first session this afternoon is, we're going to go question by question through those six questions.

And what we've asked, we asked anyone to actually provide us information about any of the questions, but to make this meeting doable in an afternoon, we've asked two of the organizations to lead off with comments for each question.

And then we'll have a period after that of about 20 minutes where we'll open it up for additional comments and questions regarding that specific question.

And then we're going to have a final session at the end of the day where we'll open this up to comments from the floor on issues even beyond those questions, issues you may want to raise about the law, its implementation. And then also, additional

open comments on those questions.

So, Kim asked that each of you, each speaker should state their name and their organization when you speak today. And please respect our time limits. The time is limited, and so you may be asked by myself to shorten or quickly wrap up your comments if I think we're going a little too over.

And we could be a little flexible at the time for comments or questions, maybe adjust depending on the progress that we make.

I want to say, this is a meeting for information gathering and discussion. It is not a meeting that by the end of the afternoon, you know, we're looking, CMS or AHRQ's looking for consensus. So it's okay if your viewpoints are different with regards to these issues.

The session, just to let you know, the session will be audio taped. That's because they want to make sure that they actually get your comments correct.

And after this meeting, if you have additional thoughts, they can be put in writing and sent to CKDEducation@cms.hhs.gov, so if you miss anything that you want to say, it can be sent in after the meeting.

And as Kim said, we'll have an executive summary of the meeting available at a future date that will be announced.

So I think we're ready to get on with the comments today. So what I'm going to ask is for each of the questions that the two speakers or two first commenters come up to this table here. Our first two are Sue Cary and Dale Singer.

And this was the first question, 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 kidney replacement therapy?

So we'll start off with Sue. And you have a PowerPoint, and I'll load it up

here for you.

MS. CARY: Thank you. I appreciate it, thank you.

All right, let me get my watch.

Hello, I'm Sue Cary, I'm President of the American Nephrology Nurses Association. And we are a membership of over 12,000 nurses, and we'd like to thank AHRQ for the opportunity to be able to speak.

Our members are employed in various areas, as you can see, federal, state, all the areas of renal replacement therapy, CKD, etcetera.

Our mission statement. Part of it is to positively influence outcomes for patients with kidney disease. And that is why we are very appreciative of being able to be here, for to be able to be partners in the quality care for patients with kidney disease, with all of you.

We are the largest professional organization in nephrology as nurses. And our

members practice in many areas. As you can see, at least over 25 percent of them, over a fourth of them, practice in CKD area.

All right, we do have question number one. And you have that question in front of you, and we decided to break it into a two part question.

One, the first part being, what are the accepted clinical criteria, or standards of practice, for diagnosing someone with Stage IV Chronic Kidney Disease?

We went to the kidney disease outcomes quality initiative, KDOQI, which all of you are familiar with. The reason that we used this is because it does provide evidence based clinical practice guidelines for all stages of chronic kidney disease.

It was an initiative started by NKF in 1997. And it's recognized throughout the world for improving the care of dialysis patients.

They also give the definition,

KDOQI gives the definition of CKD. And I'm sure most of you, all of you are familiar with that. Kidney damage for greater or equal to three months, with or without decreased GFR.

And the second part of the definition has a GFR less than 60 milliliters per minute, greater than or equal to three months, with or without kidney damage.

So, severe decrease, or stage IV chronic kidney disease, defined as severe decrease in GFR of 15 to 29, or less than 30.

The workgroup did identify though that the limitations, one of the limitations, the GFR cut-off, for stages III to V, have been selected based on limited data with respect the relationship between complications and level of GFR. Basically, when you're using the numbers as a basis, to be mindful of those who are at the borderline.

For example, someone who I actually had in CKD clinic yesterday, between 28 and 30, stage III, stage IV. But a lot of times,

you know, that would depend upon the hydration state. Check it again, another week or so it may change. So, especially those on the borderline.

Part two of question number one, the clinical criteria for determining the need to start renal replacement therapy.

Focusing on the assessment data of how the patient feels. Uremic symptoms, how uremic, are they, you know all that, are they nauseated, are they eating, et cetera. So looking at the uremic symptoms, your assessment of the patient.

Then patient preferences. Some don't want to start when you advise them to. Some are holding off as long as they can. Some don't want to start at all.

So, taking into account, when do you start renal replacement therapy? Uremic symptoms, patient preferences, and then focusing on the numbers, which I just mentioned about the definition of CKD stage

IV.

Also you look at the other numbers, hyperkalemia, anemia, fluid volume overload, metabolic acidosis, bone disease. All these numbers that become refractory to medical therapies as they near end stage.

Looking also at poor nutritional status, as the albumin keeps dropping. And then, we all know that we look at stage V chronic kidney disease with estimated GFR of less than 15 for diabetics, and less than ten for non-diabetics.

So, clinical criteria, also is determined by modality of treatment chosen. Transplant, usually start looking, putting, trying to get them evaluated for a transplant, GFR of 20 or less, not necessarily waiting for the 15 or 10.

And PD, higher GFR than hemodialysis. Since this is a self-motivated modality, don't want somebody very uremic trying to do PD. You want them to be looking

at a slightly higher GFR at this point for various reasons.

So we'd just like to thank you again. And also just to summarize, not only focus on numbers but also focusing on the patient assessment.

Thank you.

DR. POWE: Thank you, Sue. And next we'll have Dale Singer. Let's see, did you have slides?

MS. SINGER: No.

DR. POWE: Okay.

MS. SINGER: Good afternoon. My name is Dale Singer, and I am the Executive Director of the Renal Physician's Association, 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.

The question I am addressing is, 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?

We believe that RPA is ideally suited to address this issue in light of our development and publication of the evidence based clinical practice guideline in this area entitled, Appropriate Patient Preparation for Renal Replacement Therapy.

This guideline was preceded by an AHRQ endorsed evidence based report on this topic that was prepared by RPA, and the Duke University Evidence Based Practice Center for Clinical Health Policy Research.

The degree of advancement of CKD is determined by a combination of evidence of kidney damage, such as proteinuria, and level

of kidney function, as indicated by glomerular filtration rate.

The patient population at the center of the RPA's guideline, and a target group for the CKD education benefit, is the patient subset referred to as advanced CKD, a shorthand term for the more specific designation of those patients whose clinical condition is characterized as advanced chronic kidney disease stages IV and V, but not on renal replacement therapy.

This corresponds to a GFR of less than or equal to 30 milliliters per minute when kidney function is at a high risk of progression.

Natural history data indicate that when patients reach stage IV, a large percent will likely progress to stage V and require renal replacement therapy.

Prior to stage IV, the focus of diagnosis and treatment of CKD is on slowing progression of kidney failure and identifying

and managing comorbidities. As the patient progresses to stage IV and V advanced CKD, the focus shifts to managing complex metabolic disturbances and preparing the patient for dialysis or transplantation.

Proactive preparation for renal replacement therapy is recommended to facilitate the transition and reduce the burden of clinical risk factors known to be associated with worse outcomes in ESRD patients.

Stage IV CKD is defined as patients with GFR 15 to 30 milliliters per minute, renal replacement therapy usually does not begin until stage V CKD when GFR is less than or equal to 15 milliliters per minute.

Some patients with uremic symptoms, nutritional deficiencies, or other compelling factors, may require initiating dialysis in stage IV.

Some preemptive kidney transplants are performed for patients with late stage IV

to early stage V CKD when appropriate donors are identified and clinical circumstances suggest earlier rather than later transplantation.

RPA appreciates the opportunity to provide our input to the kidney disease stakeholders meeting, and will continue to serve as a resource as AHRQ and CMS work to ensure the best possible health outcomes and quality of life for Medicare beneficiaries with CKD.

DR. POWE: Thank you, thank you. Great.

So let me invite anyone who'd like to comment on this question to the microphone.

Dr. Hostetter?

DR. HOSTETTER: I agree with a lot of what's just been said.

I'd sort of put the questions back together again, that Sue took apart, because I think that seems to me, would seem to me to be one of the questions that CMS may be asking,

that is, how do we decide who really needs this kind of education? And that underlies that, it says that maybe not everybody there does.

And I think that makes it a very hard question. It makes it hard for the reasons that Paul brought up. That if all those people who have a GFR of 29, not all of them are ever going to need end stage renal disease.

Some of them are elderly and die from some other almost entirely independent comorbid condition. Others will not even be identified at that stage. And a few from acute kidney injury will drop in.

So I don't have an answer to it when I combine those two. But I have a general answer. And I think that means that we're going to need to educate far more people than need to be educated, if need is defined by those who end up on a dialysis machine, peritoneal dialysis, or having a transplant.

And I don't think that's entirely bad, because there are other messages to get to these people other than what's going to happen when they reach end stage.

But because not all 700,000 of those people will get to that stage, and we have such poor predictors for knowing that, we will be teaching people some things that maybe will never really pertain to them.

MS. WITTENBERG: Could you please also introduce yourself and state your affiliation?

DR. HOSTETTER: I'm sorry, I'm Tom Hostetter, I'm here with the American Society of Nephrology.

MS. WITTENBERG: Thank you.

DR. POWE: Would you like to comment?

MS. CARY: Just part of that, I understand what you're saying, but as far as the education of CKD stage IV, part of the goal would be also those trying to prevent

them from further progressing, which we do have, like you said, a lot of elderly, etcetera, that would not be considering going on renal replacement therapy.

But they can benefit from education at stage IV to be able to prevent progression. Not just elderly, but, you know, to prevent progression. So that's part of why we broke it into two.

DR. HOSTETTER: I agree with that. I think that would be a big benefit of this, if you could prevent them to getting that stage.

But I think, if the question really means, how do we decide whether Mrs. Jones really needs that education because Mrs. Jones is going to end up on dialysis, I think we have to say, we don't really know. We have a few clues, clinically, but we can't tell whether she's going to get from 29 down to 10 with any kind of certainty.

So we're going to have to be

willing to instruct lots of those people where we can't predict where they would go. And one of the benefits that you raised I think is a really important one, that may help to prevent her from getting down to GFR of 10.

DR. POWE: Other comments?

MS. WITTEN: I'm Beth Witten, I'm actually going to be one of the people talking to you. I'm here representing a whole bunch of people. I didn't want to go unemployed.

So I'm here with the National Kidney Foundation, but not representing them today. Dolph's doing that. I am representing Missouri Kidney Program and Medical Education Institute.

One of the things that I think is real important in educating patients is educating as many people as we can to prevent kidney failure. Because that's very expensive for Medicare. So if we can keep people, even if it's the 80 year old person, from developing kidney failure before they die,

then that's going to save Medicare money.

So I think the other thing that's important is looking at, how do we choose which patients to refer for education? Who's going to make that choice? Who decides who's a candidate for education?

I work with Missouri Kidney Program, we get referrals from all kinds of people. And one of the things that I'm concerned about a little bit with this law is that it says that only the physician can refer for CKD education, or a nurse practitioner, or basically an advanced practice registered nurse.

And we get patients who come to our classes who are self referred, because they saw a brochure and they heard about our class. There could be a way that that could be screened with a physician who then certifies the person as someone at that stage, and if we're educating people that are at stage III instead of stage IV, and that is not a

Medicare covered benefit for that person, at least they're being educated.

So, you know, I would just caution against too much narrowing down the focus on who should get the education, because if we can prevent kidney failure, slow the progression of kidney disease and save money in Medicare, it'll be to the advantage of everybody.

DR. POWE: We need you to come to the microphone.

MR. RETTIG: I'm Dick Rettig from RAND and part of Drew-RAND-UCLA Comprehensive Center for Health Disparities.

I think the implication, or to me, I guess it's a question, is not the implication, one implication of what you said, Tom, and Beth, what you said, that the statutory limitation of this education on stage IV is inappropriate.

That is to say, why should stage III not be engaged from an education

standpoint? I'd like to hear your comments.

DR. HOSTETTER: I think the President-Elect said it in one of the debates, not that I equate myself with him. But, that's above my pay grade to answer. I mean, that's a cost, because you go from 700,000 people or thereabouts, like Paul said, that's even putting aside the ones that's dropped in from acute renal failure, to seven million people.

And so, the cost would be different. And maybe I have too small a scope, but I'm sort of grateful that we're even getting it at stage IV.

But having said that, I agree with you entirely, and I think it emphasizes what Beth said, that if we could slow progression at even earlier stages, there are benefits that would accrue.

DR. POWE: Dolph.

MR. CHIANCHIANO: Dolph Chianchiano, National Kidney Foundation.

Carrying on with, from Dr. Rettig's comment, I would go the opposite direction, and that is that patients in stage V kidney disease not yet on dialysis would also benefit from these services. And it's unfortunate that the statute is so limited as far as the entitlement is concerned.

DR. POWE: Let me ask a question in follow up to this. I guess there are variety of services that Congress has spelled out in terms of the content of the education. And would that vary by the stage of disease? I think, you know, would you necessarily want to be educating all stage III patients about their options for renal replacement therapy early on at a GFR of let's say 59?

DR. HOSTETTER: I'd say no. I think the bang for the buck there would be things about slowing their progression to that stage. So then, I think that's your question, the nature of the education, or emphasis of the education in my mind would be quite

different at those early stages. And would also just include that you may not get to that place at all, but need to be followed.

MS. CARY: I would agree with that because patients coming to CKD clinic, they're really afraid of the word that you're going to mention, is dialysis or renal replacement therapy. They don't want to hear that word.

And so there's a lot more than renal replacement therapy to teach them about. So no, I wouldn't educate everyone, especially with GFR 59 on the renal replacement therapy option. But there's a lot more that they do need an education on.

DR. EGGERS: One thing I guess about this stage III is, you know, one of the sort of odd things about the staging criteria is that stages I and II, you have to have kidney injury, which is microalbuminuria.

And then all of a sudden you change the criteria and you have a whole lot of people in stage III who are there largely

because of age.

And so I think that although we don't know as much about progression as we should, I think that nephrologists in general already do this. I mean, if they've got a patient that's elderly, has no microalbuminuria, and is, you know, a 50 or 55 GFR, doesn't really worry about that sort of thing.

On the other hand, if they're say a younger patient, say 35 or 40, and has a GFR of 55, and has microalbuminuria, then that means a much different sort of thing in terms of progression.

And so, you know, it's a little hard to sort of write, you know, bureaucratic rules about that sort of thing. But I think there are a lot of indications that nephrologists have about the nature of the patient, other than just whatever the GFR is.

MS. NEWMAN: Hi, I'm Eileen Newman from the National Kidney Disease Education

Program. And our tactic is that education is a continuous process. And so, when we get a patient or we recommend a patient who has a GFR of 59 or 60, we begin kidney disease education with that patient.

And you might begin by talking about the function of the kidneys and what the detection, and go on to treatment. And as they slowly progress, if they do progress, that they do then, you do talk about dialysis.

And by giving them these, as you're seeing them more and more often and repeating this, they may not even be hearing what you're saying at the very beginning, but when they're hearing this, and they're slowly accepting some of the information that you're saying, that they then can be more prepared for dialysis as you get further and further along.

And maybe as their GFR is decreasing you can then start talking about dialysis and then have better outcomes with dialysis because they are more informed.

MS. COMPTON: I'm Ann Compton at Virginia Commonwealth University.

And with stage III CKD you have the opportunity to really slow progression, especially in those patients that are young with diabetes and hypertension. And oftentimes if you start giving them some dialysis education at that point, they may change their behavior to get their A1C better under control as well as their hypertension under control.

And that is where you can get Medicare bang for the buck, is changing those health behaviors of those individuals early on. And those two, just diabetes and hypertension.

DR. POWE: I see no more comments on question one, so I want to thank the commenters and all the others for your comments and opinions.

So we'll move on to our next group of questions. And question two, why don't I

have the two presenters come, they're Jennifer Russell and Tonya Salstrom.

Question two is, What are the different modalities of education appropriate for kidney disease education? And we'll have Jennifer Russell lead off, and we have some slides.

MS. RUSSELL: Good afternoon, I'm Jennifer St. Clair Russell with the American Kidney Fund. I'm the Director of Professional and Public Education with the American Kidney Fund.

A little bit about AKF. Many of you may be familiar with our mission, but primarily we provide direct financial assistance to kidney patients who are in need. We also provide health education to people with or at risk for kidney disease.

We have a number of programs, many of which are financial. But we also have education outreach programs. In 2007, AKF provided over one hundred million dollars in

financial assistance to 68,000 kidney patients in all 50 states.

In looking at the different modalities for patient education, it's conceivable that patient education can have multiple goals. I've listed just a few here.

Improve outcomes, obviously. But perhaps increase patient efficacy. Provide hope. Increase patient involvement in decision making. Increase patient-provider communication. There could be a number of different goals.

I think depending on those goals, and what the focus is, the components or the way that the education is delivered could vary.

At any rate though, what you're talking about when you're looking at patient education with this particular population is adult education. And adult education theories and principles.

It should be interactive, and

developed with the learner in mind. Certainly, we have things that we want to communicate to the learner, but we need to remember where they are in the process. Someone mentioned earlier they may not be ready to hear what we have to say to where they are in hearing it.

It also should be culturally appropriate. Developed certainly using health literacy principles. And appropriate for various learning styles. It should be based on their readiness to learn. And most importantly, grouped in manageable chunks.

I know sometimes we may consider that people may be coming from rural locations, and may only have access to them for one time in two or three months. So you want to group everything you can at one time. But what is the person really going to walk away with?

Typically we recommend education would only be about 45 minutes to an hour at a

time. And it should focus on three to five key points. Again, these are things that people can walk away with. And these points should be reinforced. What use is the education if no-one's going to remember it when they leave?

And then finally, include assessments and opportunities that allow learners to apply what they have learned.

The American Kidney Fund supports small group sessions as well as individual sessions. We believe a combination would be able to appropriately incorporate adult learning principles as well as some of the other benefits that come with these various modalities.

And here you see I have pros versus cons on small group sessions. Pros, of course, offers a component of support. They're with their peers, they can share their stories. Provides for richer discussion and greater interactions with peers.

Cons would be, shared medical information could be perceived as medical advice, or could taint patient perspectives. And of course there could be confidentiality concerns.

But then when we look at the one-on-one sessions, you can see that those pros and cons then flip. So wouldn't it make sense to have some flexibility and to complement the pros of those by having a combination of both?

I talked a little bit about interactivity and engaging the learner. Certainly multimedia is something that we all -- we live in a world -- I see many of us have BlackBerries or Palms that we're walking around with. This population may not be appropriate for some of that advanced technology.

In fact, as you can see on the slide, when you look at the Pew internet data, many of these folks may not have access to the internet. And certainly if they do have

access, are they going to be able to log onto a WebEx or GoToMeeting session? Some of us even have problems with that.

So, internet education may not be accessible, but certainly there are other distance education modalities that would be appropriate. Things like teleconferencing.

Certainly written materials where they could read something assuming it's at an appropriate literacy level, and then there could be some sort of assessment and a discussion perhaps over the phone or on a one and one basis.

Certainly the use of videos. Again, appealing to the multiple learning styles of your learner.

So in summary, recommend a combination of face-to-face, small group sessions along with one-on-one. Should be developed using adult learning principles. Sessions should only be about 45 minutes, focus on three to five key points. And it

should be limited to about 10 to 12 patients and include family or caregivers.

And again, if we're looking at multimedia, incorporate things like teleconferencing, videos, but limit the use of internet and computer based education just because of accessibility issues.

Thank you.

DR. POWE: Thank you. Next up we have Tonya Salstrom. Let's see, did you have slides? Okay.

MS. SALSTROM: Hi, I'm Tonya Salstrom, I'm Deputy Director for Dialysis Patient Citizens. And I am again answering, what are the different modalities of education appropriate for kidney disease and patient education?

At the risk of repeating Jennifer, most of what she has outlined as appropriate modalities, I completely agree with. But wanted to just kind of supplement some of the information with some patient examples.

I'll start out by telling you that first, DPC is a non-profit organization. We have a patient controlled board of directors, and our membership is focused on dialysis patients and pre-dialysis patients. We currently have over 22,000 members nationwide.

Our primary purpose is to develop awareness of dialysis issues, advocating for patients, and improving the partnership between patients and caregivers, and of course promoting favorable public policy.

You can see that we were overjoyed with the passage of MIPPA and the beginning of education for CKD stage IV patients. This is something that our membership supported wholeheartedly, was up on Capitol Hill talking to members of Congress about.

And we're very passionate, even though most of them were current dialysis patients, they had missed their opportunity for this education, they very much wanted to see that other patients were educated on these

issues and properly prepared for dialysis, but also to help prevent or delay dialysis for others.

So some of my slides you're going to see here are a little bit different than probably what you've seen today. These are slides that I've taken from presentations that we have given to patients. So they are a little bit comical and cartoonish.

But I think they're appropriate, because one of the things that you're going to want to do for education is you really want to empower patients. And to do that, you're going to have to be able to present education in a manner that is understandable to the population that you are working with.

The population is diverse as has already been outlined here today. And there are different levels of education and different levels of, different ways that people learn. And so one of the ways that people learn is by visual aids. So you will

see some, most of my slides are just a visual aid for you.

What I think the focus on education is, you want to empower individuals. And the empowerment is important because what you're doing is you're educating them to take better care of themselves. Once they've been educated, they need to feel that they can apply that to their lifestyle.

So we feel that a combination of education principles is best for patients. So a combination of written materials, you can do internet education, face-to-face education, video education. All of this can be incorporated, but the importance here is it needs to be personalized education.

So all of these pictures that you're seeing up there are current patients. You can see how diverse the population is. You have younger, older, you can't see it here but you have lower income, different education levels.

So it's very important to educate in a way that speaks to them. Your senior citizens, your Medicare beneficiaries, are probably not wired, as Jennifer said. They didn't grow up wired, they're not used to accessing the internet for education.

But your younger patients, those that are in their 20s that are maybe dealing with high blood pressure and that's how their kidneys are failing as a result, they may be very comfortable with the internet.

They are already online trying to figure out what has happened to them. They are looking on FaceBook, they are searching Wikipedia, so they are very comfortable. And so in that respect, internet education would be appropriate for that population.

In some other areas of the country you have high illiteracy rates. And for those people the face-to-face education, small group sessions, one-on-one with a clinical educator or a nephrologist, is going to be a

little bit more appropriate.

No matter what method of education is chosen, the importance is really going to be on focusing on comprehension, understanding, and reinforcement. They are going to need to be able to take that education home with them and apply it to their daily lives.

And one way you can do that is by incorporating different ways to test their knowledge. But also in developing a patient care plan. Now these can come again in different formats. They can be written. They can be something that's done in a quiz online. They can be something that's discussed one-on-one.

But whoever is providing the education is comfortable and knows that the patient has understood what has been brought to them, and that they can then communicate back to the educator how they can incorporate what they've learned into their daily lives,

is going to be extremely important.

One thing that I hear so much from patients is, if I had only known. If I had only known that if I didn't take my blood pressure medicine properly, my kidneys could fail.

I work with a 27 year old, and he's a patient ambassador of ours. And this is a little bit about that Patient Ambassador Program up on the screen. Basically it's patients that are educating other patients in their dialysis clinics in their local communities to raise awareness about kidney disease.

Twenty-seven years old, has high blood pressure. Took his medication, started to feel better, so he stopped taking the medication. It's not a cheap drug, so he stopped taking it. And then went back to the doctor and found out that his kidneys were failing, and he was going to need to go on dialysis.

And of course he comes to us and says, if I'd only known. And now he has made it his mission to educate others in his family. To raise awareness in his community, that hey, this can happen to you.

And so I think it's important when you're providing education to patients, that it is done so in a manner that's understandable to them, because it is ongoing. And that also it can be provided with a support system in place.

So I think that if you're going to provide education, a family member should attend the sessions. Whether they're in person, online, they should be present. Because then that's somebody you can go home and talk to afterwards and start to really develop a family or a companion or friend support system.

And these are just some quotes of what patients have said. Patient to patient education doesn't replace clinical education,

but it can be an added support value. So I think after addressing initial modalities of education, and introducing patients in a group setting, and helping them foster ongoing relationships so that they can talk to one another and help educate other patients in the future, would also be a way to promote greater outcomes.

So, I would like to thank AHRQ for having us here, and I'm very excited for the legislation, and I'm glad that we've already started working on this discussion.

Thank you very much.

DR. POWE: Thank you. So let me open the floor up to additional comments and questions.

MS. CARY: I actually just have a comment. Some of the words, I think three words that were used by both of you that was very important: personalized, individualized, and culturally appropriate.

A few years ago, ANNA had looked

for what information was out there for patients in the Spanish population for instance, and there's a lot of information out there. But culturally appropriate is very important.

The individualized. Just yesterday I had a woman that was deaf. You know, so you have to -- a lot of -- I think those three words, culturally appropriate, individualized, and personalized, are very important to consider when they're looking at this question.

MS. WITTENBERG: And Sue, please state your name and affiliation.

MS. CARY: I'm sorry. I'm Sue Cary, ANNA President. Thank you.

MS. KITSEN: Jenny Kitsen, Director for the Network of New England.

I just wanted to make the observation that I think particularly when you look at the demographics as Paul was mentioning in terms of the Medicare patients

who are in stage IV that we're discussing here, we're really talking a disproportionate number of geriatric patients who live within the system and a family.

And I think in terms of these educational models that we're thinking about, we really need to consider the fact that we're not just teaching the patient, we're really trying to teach the significant other and the family support system that's with them.

Because they're going to be just as involved in this chronic illness as anyone else is, and they're going to have to be supporting and helping that particular patient.

Recall, remember, and you know, follow the adaptation and the changes that are going to be needed with regards to moving forward into the next stages and selecting modalities that are appropriate for them.

So I think it's, we're talking a unit here, were not just talking a patient.

MS. COMPTON: Ann Compton, Virginia Commonwealth University.

I just wanted to say that the assumption that education level has anything to do with health literacy should be taken away, because the truth is, everybody kind of starts at the same level.

I was telling Beth, I have a cousin who is a health educator from Johns Hopkins, and has a Masters there, and doesn't, can't even tell you the medicines he's on right now because of the illness and what it's done.

So, you know, we have to assume that everybody at an equal level, and drop those levels of education to suit everyone but not assume that just because you have higher education that you're going to understand better.

DR. POWE: Great commentary. Let me ask a question. Both of you talked about small group sessions. What is a small group session? How big or small should be a session

be? Is there too large a group for which this would be ineffective?

MS. SALSTROM: Sure. I can give you some examples. I would say probably try to keep it under 20 people. And this is one thing I had meant to address.

Where you have the group sessions is going to be very important. Utilization of community health centers would be an excellent place to hold these type of education sessions, because they are easier to access for patients, patients may already be familiar with them. And maybe receiving other services at the community health center.

I think once you get above 20, you do find it a little bit difficult for everybody to ask the questions that they might have. I know we hold conference calls on a monthly basis with current patients, and we get about 30 to 50 people on those calls each month.

And when you do that it's great and

everybody is receiving the information, but not everybody is having the opportunity to get their question across. And so you run into that challenge.

DR. POWE: Thank you.

MS. RUSSELL: I would agree. I think 10 to 12 folks, groups of 10 to 12 people as well as including family members, so maybe no larger than 20.

And of course it also can affect how interactive, not only just asking questions, but if you're going to be doing care plans and things like that, the educator needs to be able to talk to the people participating, the family as well as the patient, and provide some direct one-on-one in the middle of the group sessions as well. So I think smaller groups about that size would be best.

MS. NEWMAN: Eileen Newman. I would just like to add to --

DR. POWE: Just repeat your name

and --

MS. NEWMAN: Eileen Newman, National Kidney Disease Education Program.

I just would like to put a focus on the providers, or the, who is providing the education. It's important not only to think of the, you know, the physician, but also nurse practitioners, registered dieticians, social workers, nurses, advanced practice nurses, the many, many different types of people that can be involved, and to make sure the legislation includes all those types of providers that are able to do that.

DR. POWE: Yes?

MS. BASINGER: I'm Karen Basinger, I'm a member of the Renal Practice Group and --

DR. POWE: Can you just wait one second?

MS. BASINGER: Sure.

DR. POWE: She wanted to make a comment related to that prior comment.

MS. RUSSELL: I just wanted to add, certainly education should be multi-disciplinary because that is how ultimately renal replacement therapy is delivered. But I think also you need to think outside of the box and realize that just because someone is a content expert or a subject matter expert does not make them an educator.

And so a lot of folks may not be aware of adult learning principles, may not be aware of those three things that we have hitting home in our presentation. And so it has to be a team approach, not only in the way care is delivered, but also in the way education is delivered.

DR. POWE: Thank you. Sorry to interrupt you. Now you're on.

MS. BASINGER: I'm Karen Basinger, I'm a member of the Renal Practice Group of the American Dietetic Association.

This is from personal, this is my other hat. I actually work in a senior

retirement community. And we do classes regularly. And we keep them at five, but we have more, we have family members and care givers and everything in there. So our little room maybe can handle ten. But actually it's five people in there, and it is, it's a small, small group. And we cover maybe one out of three topics, but it's what they can handle at the time and what they discuss.

Sometimes I have to pull somebody aside and do some more one-on-one. It's about personalizing. It's about working with people. And especially the one thing I have to emphasize is, with the elderly, they have a hard time hearing. So when people have a certain, they have a dialect, or they have a strong accent, the message isn't received well. And in fact, I've had them walk out the room when we use somebody with a very strong accent, and had to repeat the session.

So I think we need to be not only culturally sensitive to the material that we

have, but culturally sensitive to our learners. Because the accents are very hard for the elderly to understand.

And when I see this group, it's not four or five sessions. Because they're staying power isn't lasting long. It may take me ten sessions. So that's why when I see this for six, the number of sessions, that also impacts on what we can do.

MS. SALSTROM: I agree, the number of sessions is going to be problematic, particularly if they're going to be face-to-face sessions.

Because particularly in rural areas, and those of you that are in the dialysis industry already realize that transportation to dialysis is problematic. So transportation for something that's going to be voluntary is going to be a nightmare. And you're not going to get the number of people there that you need to educate.

If it's, you know, a total of six

sessions, maybe it needs to be, like we both mentioned, other formats of education or combined. Something needs to be addressed so that they are not just six sessions that are face-to-face in a doctor's office.

MS. RUSSELL: This also appeals to different learning types as well.

MS. WILLIAMS: Hi, Deb Williams, Baxter Healthcare.

You know, we've had a longstanding program of kidney education and other people too, however, I think the way the benefit is constructed in the statute, it's under the physician fee schedule, and it's envisioned as a clinical service where the only person who can be responsible for the payment is the physician, the nurse practitioner, or the physician assistant.

So if you think about it in the constructs of the Medicare program, that people can still go out and do community education, but that's not what's under this

clinical benefit.

Matter of fact, I would hope that we and others still do, you know, community education. That way you could tell people, you can go into your nephrologist for more intensive sessions.

But the kind of face-to-face sessions in a physician's office, which by of necessity, just practical necessity, the size of the office, will relatively be fairly small, is a different kettle of fish, can of worms, I don't know, something like that.

Thanks.

DR. POWE: And again, it may not exclude one of those providers that you mentioned bringing in others as --

MS. WILLIAMS: Yes.

DR. POWE: -- part of the education session.

MS. WILLIAMS: I think that we believe that that's very important that the physician be allowed, the benefit be rich

enough, the physician be allowed to bring in -- - first of all, they may not have a trained nephrology nurse to do certain things, dieticians, clinical social workers to talk about you know the psycho-social elements. Those are all very important.

DR. POWE: Thank you.

MS. HAYS: My name is Rebecca Hays, I'm a renal social worker actually out of Transplant Center University of Wisconsin.

Thank you for your presentations.

You know, Jennifer, when you were talking about patient readiness to learn, I think that was where my ears really perked up, because I think that's one of the challenges to thinking about this education, is considering that folks in stage IV are going to still be in the beginning phases of disease adjustment.

And so I think for this education to hit home it needs to be targeted to what people are ready to learn and what people are

going to be excited to learn about.

And I think that's often protecting their sense of vitality and also protecting their quality of life. And so I think if we can offer this education to target what people's goals are at that point, they're going to be more likely to participate.

DR. POWE: Yes.

MS. RUSSELL: I think that also speaks to, that the number one concern may not be necessarily what modality of therapy they're going to go on. They may be wondering how they're going to pay for this.

So, I think that's again where it goes back to personalization and starting where the learner is. Because you need to address all those barriers and all those concerns first before they're going to hear anything else that you're going to say. So, absolutely, I agree.

DR. POWE: Yes.

MR. RETTIG: Dick Rettig, RAND

Health. I'm impressed by the dominance of this discussion of a professional education model. I kind of have some of the same reactions I had to teacher education as a sort of root cause of problems in schools.

Let me tell you, we have a report that will come out in some time in the Spring I expect. Six cases of CKD clinics and practices. One of those practices focuses on Paul Crawford in the southwest side of Chicago.

Paul is an African American who grew up in the southwest side of Chicago, and came back to live there to serve his community. He goes everywhere, to every church, to every community organization. He speaks on television and radio as frequently as he can.

The Baxter representative mentioned community outreach. I think at some point you've got to just say, the model that's implicit in the question here is only

partially adequate to the problem of educating in the community to the concerns for diabetes, high blood pressure, and so on.

And I was struck the other day by the piece in the New York Times, November 20, enlisting the aid of hairstylists as sentinels for domestic abuse. And you can read the comments that follow that piece, and there's some that quarrel with the thing, but there are many that are really quite supportive.

And I haven't heard anything in the modalities about beauty parlors and hair salons as a way to get the information out. And I think in the Black community that's certainly a very important thing.

MS. COMPTON: This is Ann Compton, VCU, again. I don't see these as mutually exclusive. I see, you know, what the law says as far as nurse practitioners, and doctors, and physician education.

But also I think there's a very important place for these other education

programs that have been implemented through the years that have been very successful in patient education.

So I don't see these as mutually exclusive, I see them existing alongside each other.

DR. HOSTETTER: Tom Hostetter, ASN. First a comment, and then a question for the panelists.

I realize we're not here to design the content of this education program, but I would really urge that there be more than lip service to two pieces of it. We keep talking more about dialysis, preparation for dialysis, choosing modality of dialysis.

But one is that these people at least at the higher ends of GFR may be able to delay it for a significant period of time and save the system money, at least 60 or 70 thousand dollars a year that they're off of dialysis themselves, I'll agree.

The other topic that needs to be in

there again as more than lip service is early transplantation, which may not be in the interest of a lot of the people who would be delivering this message, and who would bill for it.

And so, while it kind of shows up on the list, I think it's more often lip service to really urging patients to looking for relatives or friends that could donate.

The question I have for the panelists is, how effective would it be to do these in dialysis units? I worry about that a bit. A friend of mine once said, it's like CKD education in the dialysis unit is doing marriage counseling in a divorce court, in that the patients are very afraid of it, that it's not the place to do it.

I also am afraid of it because it may be a way of channeling, using dialysis units to channel patients into given providers or different clinics, which I don't think would be a good use of this education benefit.

So I'd like to hear the panelists' discussion of the use of dialysis clinics as sites for this.

MS. RUSSELL: I would agree with what Tonya said earlier, using community health centers and places out in the community. I think that also brings in the point about community outreach and going out into the community. I would agree that I think if you're delivering this education in a dialysis center it tends to look like you're trying to sway them towards a particular type of treatment.

I think however there could be some usefulness in maybe a visit. But certainly not all the education sessions delivered there. And I think the one thing too is, to go back to this one point that we made over here, this is not, education obviously, patient education, is not new.

Education in barber shops and beauty shops is not new. That's where a lot

of breast cancer screening has started. Many model programs in the health education world have started in churches and in health centers, beauty shops, and that sort of thing.

So, and I think it goes back to the point that we made over here is that we can do all this stuff in tandem, and then hopefully these are well informed patients and families that then can ask the questions that, and get the information they need, in these sessions then that would be paid for by Medicare.

MS. SALSTROM: I'm going to agree. I don't think that a dialysis clinic is the proper place for all of these education sessions. I do see a benefit in, like Jennifer said, a visit. I do also see the benefit in a dialysis patient meeting with a CKD stage IV patient and discussing not just dialysis but discussing how they ended up on dialysis.

So where your focus may not be, how do you prepare for dialysis, but here are

some steps that you can take to prevent or delay that I didn't know about before. And that's very powerful.

We actually have had a lot of experience with patients going out to their local churches and their local communities and doing just that. Talking to those that have diabetes, those that are at risk for kidney disease, and saying, like I said before, hey, if I had only known. And they really have a passion for doing that.

And back to, I don't remember her name, but she was saying, there are definitely these six sessions that need to take place. And there are six topics that need to be discussed at CKD stage IV. But there's still a variety of issues that need to be addressed. And continuing education is also very important.

DR. POWE: Well, I want to thank our commenters and all of you for those. Also, thank you for staying on time. We're

actually on time in this agenda, which is very nice.

So, let me have our commentators for question three come forward, Ann Compton and Beth Witten.

The question three is, what is the recommended frequency and duration for these education services? And I think we began to touch that a little here.

MS. COMPTON: I cover two of those positions, I'm a Nurse Practitioner and a Clinical Nurse Specialist. So that kind of helps me out.

So I actually have had a patient education program at VCU since 1997. A health educator dropped in our lap that was doing her PhD in education and developed our education to at a fourth to fifth grade level. And it was, happened to be six sessions. And we met weekly for one hour before the renal clinic, where the indigent patients, because they were there, it made it convenient for them.

So, in the literature, nothing really talked about, you know, what would work for patients time-wise or otherwise. But as far as the frequency, you want to consider your patient circumstances, the stage of chronic kidney disease, either early IV or late V, you're certainly going to talk about different things first in those situations.

What their travel time is. Do they have jobs? Are you interfering with work hours? Children, readiness to learn, in other words, you need to benefit the patient so they're not worrying about getting to their on time or picking up their children. And again, readiness to learn, what you have to say.

The teaching environment, we've talked about a little bit, is very important. You don't want it to be someplace that makes them feel nervous or whatever. You might want to offer cookies or something, just to kind of make them feel more comfortable.

Convenience to another appointment

that they have or convenience of time for their circumstances.

Health educators, you know, not all of us are health educators whether we're physicians, nurses, or whatever. It's a whole different type of thing, and we don't always, giving people this didactic learning doesn't always work. That's not necessarily what they're going to hear.

And I do believe it needs to be multi-disciplinary. Again, these six sessions don't have to exclude other things that are already being done. And I think we need to kind of think about that.

We need to be available to spend the time and have patients not feel rushed. Again, most convenient for the participants.

And also, consistent times with continuously rotating topics. In other words, every Tuesday there was a class, and it rotated through the classes over and over again, so the patients knew from 11 to 12 this

class was taking place, and they were welcome to come and bring family members. So that kind of they always knew that they had that, and they would get cookies, and something to drink.

Duration, the only thing I could find that would make a commitment about this, Sue, was ANNA core curriculum. It said chronic kidney disease have short attention spans, and so do the nurses and physicians. About 10 to 15 minute sessions are about all that we or they can handle.

They may have depressed mentation. They have a lot on their mind. They may be thinking about how are we going to afford this, what is this going to mean to my job, what is this going to mean to my family. We have to get past all of that that's going on in their mind before they're going to be able to accept what we have to say about chronic kidney disease, vascular access, the values or whatever.

Need frequent clarification and reassurance, and they better respond to repetitive information presented in varied forms. And again, that might be the sessions that we're talking about here, with supplemented by other CKD programs that are in existence now.

Again, present points early and repetitively, so that first 10 to 15 minutes you want to make sure you get your point across before you start to discuss other things.

A nonthreatening environment, some place that they can feel comfortable.

Educators should not seem hurried or distracted.

Allow adequate time to answer their questions. And they may be questions that you had no idea were on their mind.

And deal with patient concerns first so they can accept the information that he needs to make an informed decision about

his modality selection.

Our CKD education program again is six one-hour sessions.

Convenient time prior to renal clinic.

There's a consistent schedule.

They can attend class in any order, or as many times as they needed. I had one patient that came back ten times.

Significant others are welcome.

Incentives, such as, you'll get to see the doctor first. I'm always bribing patients, you can get a cookie or juice.

And again, multi-disciplinary, all of the literature says multi-disciplinary is an important part of the health education.

That's it.

MS. WITTEN: Okay, first of all, like I said before, I'm Beth Witten. I work with the National Kidney Foundation. I consult with the Missouri Kidney Program and with Medical Education Institute.

I was asked to talk on question number three, which deals with the frequency and duration. And so I thought, well, where can I go to get information? I think I'll talk about the program that I consult with.

So that's Missouri Kidney Program's Patient Education Program. It's been in existence for 25 years. I'm not sure if that's the longest running CKD education program, but if it's not the longest running, it certainly has to be up there.

It is state funded, so that we are able to provide education according to our budget.

We started in a facility in St. Louis under a cost containment grant through the state kidney program. It did cost save, because it encouraged people to do other modalities other than in-center hemodialysis. It expanded to Kansas City, which is where I am, and to outlying areas of Missouri.

We've educated about 3,000 patients

plus their family members, some of whom are also at risk of CKD. And they have expressed excitement about learning things that may prolong their kidney function.

We do, like most people do, six classes. They're one hour. Their fact based education.

They're highly interactive. We have a nurse that presents on some topics, a dietician that presents on the diet and kidney disease. Social worker moderates the classes, and also presents on financing and coping.

For the options classes, we have patient presenters as well as the nurses, so that the patients can hear from people that are actually doing the particular treatment that they are considering doing.

One of the things that we found with our classes is that patients sometimes come to them and they believe already that they're not a candidate for a particular modality. Their doctor's steering them toward

a particular modality, and we're having to overcome those kinds of biases.

I'm proposing here, and it probably won't fly, but I threw it out here anyway. Looking at the diabetes self management education, in addition to the six sessions, that there be individual counseling with the various modalities so that the patients can get their unique questions answered.

And then diabetes self management education also has a two hour annual session where the person can kind of brush up on what they maybe missed out on or forgot about from what they learned in the classes that they attended.

The way that the Missouri Kidney Program is structured, it's education that's been kind of based on what the community needs are, the patient's needs in the community. It started off with one class per week. An hour, it was usually done in the evening so that working patients and their families could

come.

But then the elderly people didn't like driving at night. So, you know, they've done it in different communities, say like on two successive Saturdays. The way that we're currently doing it all throughout the state of Missouri is three topics on Saturday and three topics on Sunday.

We found that the patients are more likely to attend that way, and they are more likely to bring their family members with them. And then if they can't attend one day, or they can't attend a particular topic, then we invite them back for three additional times. So we send out invitations to them.

And it really helps when their doctor tells them, this is a really good program, it's really good for you to go. Because then they'll call me and they'll say, my doctor suggested that I come to your class, and I want to sign up for it.

This is our schedule, this is the

way we lay out our agenda. We have 15 minute breaks in between each one of the topics, so that people can talk to the presenter or talk to the patients that are there, or talk to each other.

We have kidney friendly snacks, so they can see that you can eat things that are other than a little teeny tiny glass of water and maybe a little bit of bread.

We have an evaluation and include a pre-test and a post-test in the evaluation, so that we can see whether or not we've improved knowledge, scores. We do them every other month in Kansas City and St. Louis.

We have been doing them in Springfield, quarterly, and in rural Missouri we just had our first class in a rural location. Because we're trying to get to the rural patients and the patients that are frequently under-served.

Our northwest Missouri site, we used to do education, and currently it's

inactive. We hope to get that started again at some point.

We also send home with all the people that come to our classes a binder of materials. I brought it here, and I can leave it with you if you'd like. It includes all the PowerPoints of all of our presentations. And it includes a variety of materials from a bunch of other organizations. Generally don't include things from the manufacturers.

There's a transplant facility list, so that people know the transplant facilities in the state. We have a variety of websites and a bunch of other information that we give them as well.

Our outcomes show significant improvement in their knowledge scores. One of the benefits of this kind of education is the empowerment and the self management. That's one of the, those are goals that we have to help encourage them to choose healthy lifestyle behaviors, hopefully to prolong

their kidney function.

Ninety-five plus percent of the people that attend our classes rate them as excellent or good, in spite of the fact that they're an hour long per class, and three hours plus break times on Saturdays and Sundays.

The interesting thing is that we have a significant number of people that want to choose one of the modalities that is currently under-utilized. Instead of having 90-plus percent of people on in-center hemodialysis, we have 46 percent that say that they want to choose PD.

We're going to be following up with those patients to find out what they actually choose. We have got a research project that we're doing right now.

And seven percent of the people that attended our classes over the last year said that they want to do home hemodialysis. So that's pretty significant increase over the

number that are currently doing them.

And then we have 99 percent of our patients, greater than that, say that they would refer other people to our classes. We encourage them to go back and tell their doctors, and that's one of the ways we get the doctors to refer to us.

So these are some testimonials. I just wanted to share those with you. These are some of the words of the patients who attended our class in 2007.

And I really appreciate being able to come here and talk with you about Missouri Kidney Program and what it's done over the last 25 years. And believe that this is a great opportunity to share information among ourselves.

DR. POWE: So let me open this up then for additional comments or questions.

DR. EGGERS: Not to be a spoil-sport about the whole thing, but it says here that under the provisions of the law, no

individual shall be furnished more than six sessions of kidney disease education services.

Does that kind of answer the question already for us? I mean, is there any flexibility? Sounds like it doesn't make any difference if everybody in the room said ten was the minimum necessary, if the law says you can't give any more than six, there you go, right?

DR. POWE: The law says you can't get paid for more than six, probably.

DR. EGGERS: Well --

DR. POWE: It doesn't say you can't give more than six. And that's an issue, kind of, what that would mean. But again, I think the question that Paul's asking is, is this really reasonable, can we do it in six sessions?

DR. EGGERS: Or maybe the charge should be, regardless of what we think should be done, how can we design something that gives the maximum amount in six?

MS. WITTEN: Well, Missouri Kidney Program's been doing six sessions for the last 25 years. So, and patients feel like they -- They rate it highly, their knowledge increases significantly.

Actually, I meant to mention that when patients come in to the Missouri Kidney Program, we give them a pretest. There are 24 questions on the pretest. The patients' average score coming in is less than 50 percent, which is pretty horrible if you think about what kind of education we're providing to people that their doctors believe that they're going to be starting dialysis in the next say six months.

All of the people that we target are stage IV CKD. So we are targeting the people that this law is, you know, is targeting as well.

MS. COMPTON: Can I just say --

DR. POWE: Yes, go ahead.

MS. COMPTON: Can I say one more

thing? And I'll be a spoilsport too.

All the literature that looks at CKD education in Italy and Britain and Canada, it really impacts a patient's, if you're looking at how long they live or whatever, only about six months. You see an improvement in those patients who did versus didn't.

So another thing to think about is, keeping patients off dialysis longer, what's going to be the most bang for the buck as far as Medicare is concerned? And that is, getting these patients changing their health behaviors. They got to this place doing something. And changing and maybe zeroing in on those health behaviors to be able to slow the progression of their disease. And to have them prepare for dialysis once they do go on dialysis.

I don't see these, I said earlier, I don't see these as mutually exclusive. I see these as maybe complementing each other. The six sessions. But that doesn't mean that

other CKD education programs that are already in existence can't enhance what they learn in those six sessions.

MS. SALSTROM: I just have a quick question about the Missouri Program. I'm Tonya Salstrom with Dialysis Patient Citizens.

Beth, you mentioned that you do three sessions on Saturday, and then they get three sessions on Sunday. And you did answer part of my question when you said you did a pretest.

I'm assuming you give a post-test, and when is that post-test delivered? And is there additional follow-up maybe a month or two months out to see what the retention was?

MS. WITTEN: We give a pretest, as I said, and we do give a post-test. We give the post-test on the last day after the last session. And at this point, no, there is not a follow-up to see what they retain. That's a good point.

And that would be a good thing to

do as well as following up to see whether those patients that said they wanted to do a particular modality really actually were allowed to do that.

And so that's one of the research things that we're doing this year, is to follow-up with them on what they ended up doing. That's going to be like in six months and a year and over a period of time.

MS. SALSTROM: Great. And I think that that is very important when we're talking about education to again follow-up and make sure that there was retention there.

And that the education is implemented. Because if the idea here, which I am assuming it is, is to increase quality and reduce costs, we're going to have to have some sort of, whether it's paid for or not, there's going to have to be some sort of follow-up to ensure that the education is being put into play by patients.

MS. WITTEN: One reason why this

program in Missouri was expanded to the state related to the cost of treatment for treating somebody in-center on hemodialysis, versus treating somebody at home on PD or home hemo.

Because the cost of treating people at home and transplant are less expensive for Medicare than treating somebody in-center.

So the idea was if we can encourage more people to take more interest in their care and be more involved in their care and perhaps choose a home modality, or even to choose healthier behaviors, so if they don't have the complications it'll be less expensive.

MS. BASINGER: Karen Basinger, member of the Renal Practice Group of the American Dietetic Association.

I like to go along with Beth's devil's advocate, in that playing on the four, the additional hours. Even though you may have a session for diet, let me emphasize, that there is a benefit under Medicare for

CKD, for early dietary intervention that has been lost in this legislation.

And we really would like to make a point, that these people can come, you know, for a certain amount of education, early intervention, and they have the follow-up. Each year with a dietician, individually, or as a group session.

And I think we really need to bring out that there are other parameters, that they can meet with other people of the team separate from this six hour session, that would really help that patient do much better.

I have to tell you, in my setting, we've kept off 50 percent of the clients we've seen in five years. They are not any further in stage IV, just by diet and education.

So, and these are the senior population. So it can be done. But you need to bring in the other disciplines, and that's why I'm encouraging MNT has to be part of this.

MS. WITTEN: Well I think nobody's saying, thank goodness, that medical nutrition therapy should go away just because of this benefit. I think that more, I hope that more dieticians get out and get the provider numbers to be able to do that.

In my community I have had so many patients that have called and said, well I'd like to meet with the dietician, and then trying to find a dietician that has a Medicare provider number and does medical nutrition therapy. Thank goodness I know of two now so I can tell people, you know, there are at least these two, we're looking at trying to find more.

That is a tremendous benefit, and that by itself can help to prolong kidney function. So, very important benefit.

DR. POWE: Let me ask a question. Is the five hour session the length of this session? I noticed that these questions were about the length of this session this

afternoon. Is that appropriate given that we heard that the attention span of a CKD patient is 10 to 15 minutes? Is an hour too long?

MS. WITTEN: The patients that come to our class, they may say, "oh my God, it's that long on Saturday and Sunday?" But then, after the last day, after the last class, they're standing around talking.

They're talking to the patients, they're talking to the presenters. You know, they're standing out in the parking lot talking to people. So, I think it empowers them to ask more questions.

MS. COMPTON: There's only one way to know that, and to see if the information you gave about transplant, PD, the modalities or whatever, if they actually choose those and actually start doing them. So, you know, you have to have that follow-up.

I've had patients change their mind on the operating room table about whether they're going to have a fistula or PD

catheter, actually.

So, you know, we really do need -- And the only thing that's going to tell you if what you're doing educational-wise, and there is nothing out there, is working, is if you have follow-up to see if they actually did, or, you know, what they did, and if they got started early and how they're access placed and those kinds of things.

I don't think we know.

DR. HOSTETTER: Tom Hostetter. This serves as just a little factoid that bears on that.

About a year ago, from our place, Sue Halpern, one of the epidemiologists looked at the NHANES data. And if you take people that are less than 65, who have chronic kidney disease of this range, and who do not have a history or evidence of a stroke, they have significant cognitive impairment already.

So, I don't think, I mean, that doesn't kind of make you throw in the towel.

Obviously you all haven't thrown in the towel. It seems to me that that really needs to be considered in this group. Because they're not going to be thinking as well as other people.

That would seem, intuitively, I don't know if there's data, that that's a strong reason for having a healthy family member come whenever possible to kind of provide some kind of cognitive bulwark to these people's problems.

MS. WITTEN: Well, you know, we tell patients, when they call us and they say, we'd like to come to your class, I'll say, no, are you going to bring a family member, friend, somebody that's a support person with you?

I say, you know, four ears are better than two. And, you know, there are going to be things that you'll forget that they'll be able to help remind you.

And also having a support person there as somebody to supplement the education

and remind them in a nice way hopefully of things that are helpful to them, things that would be better choices.

MS. WILLIAMS: I don't want to correlate --

DR. POWE: Just repeat your name.

MS. WILLIAMS: Deborah Williams, Baxter. But it is true that central Missouri, and St. Louis, is one of the higher areas for peritoneal dialysis in the country, as well as around -- and of course we attribute that they have great clinical leadership in those areas too.

MS. WITTEN: Keep in mind I'm in Kansas City, so. I'm in western Missouri, but central Missouri is University of Missouri, and they have actually a different educator doing individual education with people separate from Missouri Kidney Program, because they're with one of the providers.

MS. HAYS: I'm Rebecca Hays from the University of Wisconsin again. And I

guess I would also suggest, Beth, that one of the strengths of the Missouri Kidney Program has been its flexibility to change the timing of its sessions according to what the population needs at that point.

Because I think as we begin to think about this curriculum, one of the things we should be trying to look at is who isn't getting to those programs and how to help folks get there and also see the benefit of getting there.

I would also suggest that as terrific as any of this curriculum is going to be, perhaps its main intention is to get people interested enough in the content to go back to their nephrologist and talk more about it.

And if perhaps the primary goal of this intervention should be to help people make an informed choice about their first modality choice, so that Medicare doesn't have the added expense and the person have the

added burden of switching modalities repeatedly.

And certainly, coming from a transplant center, I am biased to have this curriculum also improve our absolutely abysmal rate of preemptive transplants in this country. So, I would add that.

MS. WITTEN: And that's what we're studying, actually, in the Missouri Kidney Program, for this year and next year. Actually it's a three year grant with Amy Waterman to study preemptive transplant, and just transplant in general.

And whether the education, the way it's given, whether it's the standard education that Missouri Kidney Program has given, which is modified every year and improved with feedback from the people that are presenting, but also two different modalities of education using a video or using a health educator instead of a transplant coordinator to do the education, whether that

makes a difference.

And whether people choose to get evaluated for a transplant and then follow through on getting evaluated.

MS. COMPTON: I just want to say, in our program, we did have a transplant -- We have a dietician, multi-disciplinary pharmacist, social worker, transplant coordinator, all the other dialysis modalities, and what kidney disease is all about. So it is truly a multi-disciplinary program. And we do have a pretty good preemptive transplant rate.

DR. POWE: Thank you for bringing the perspective of transplants to this.

There are no more comments on question three. I think you earned a 12 minute break. We'll reconvene at three. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:49 p.m. and resumed at 3:02 p.m.)

DR. POWE: Okay, let's resume. I just, one housekeeping detail that I wanted to let you know. For taxi information, at the, where you checked in today, there is actually a phone where you can call one of four taxis. They have sheets like this there. Barwood, Action, Regency or the Shuttle, for taxi services. So if you wanted to do that, that's where you can do it, at the desk where you checked in.

So, we're on next to question four. And question four is, what factors in existing education programs lead to the best patient outcomes? And I think it's interesting, given the comments that we heard in the last section about measuring what happens as a result of education, that this question is here.

And so we have Dolph Chianchiano, who will be our first speaker.

MR. CHIANCHIANO: Thank you, Dr. Powe. And I thank folks from CMS and AHRQ for

the opportunity to meet with you this afternoon.

The good news is twofold, and that is that a lot of the points that I had planned to make have already been made. But the good news is that shows there's a lot of consistency in our feelings towards the implementation of this benefit.

It also means that my talk will be a little bit shorter. That's always the danger of being the seventh speaker anyway.

So, for those of you who don't know, the National Kidney Foundation is a voluntary, non-profit health organization dedicated to preventing kidney and urinary tract diseases, improving the health and well-being of individuals and families affected by those diseases, and increasing the availability of all organs for transplantation.

To give you an idea of our membership, we have constituent councils, the

patient and family council, the transaction council, the chair of the transaction council, which represents kidney recipients, kidney transplant recipients. If Debra Washington is in the room, she may have some comments later on today.

And we have professional councils on dietetics, social work, and nurses and technicians, advanced practitioners, and then almost 3,000 physician members.

Our education programs are, needless to say, patient centered. And the history of that as relevant to this afternoon's discussion begins 15 years ago with the creation of a video series called People Like Us.

Interestingly enough, there are six videos. The measure, the number six seems to be very prominent in these days.

But you can see that the effort, which I will come back to, to provide equal time for all modalities of treatment is

evidenced in the way the People Like Us video series was developed.

So there is a separate video on hemodialysis, a separate video on peritoneal dialysis, and a separate video on transplantation.

Our patient education program is based on the philosophy of knowledge, choice, and control. In other words, patient empowerment.

After the successful operation of the People Like Us video series, we developed something called People Like Us Live, which once again has six sessions. And they parallel the sessions in the video program.

It was offered and has been offered by affiliates throughout the country. It is modeled after and adopted from the Missouri Kidney Program Patient Education Program that Beth had described.

And similarly, it is implemented by a social worker moderator, who receives

training and certification by the National Kidney Foundation and the faculty is multi-disciplinary.

And the patients receive supplementary take-home patient education materials.

We believe, I think we can safely say that the People Like Us and People Like Us Live are recognized for their comprehensive content and fair balance.

So, you know, basically I'm going to talk about what are the components of a successful program. But first of all, we have to decide, what is success? And one way to look at that is, success in helping patients to cope. Because coping is important to the health outcomes for the individuals who are involved.

In the qualitative study that was done by the National Kidney Foundation of Alabama, shows that almost 100 percent of all the participants in the People Like Us Live

program found that it contributed to their ability to cope with their disease, and to manage their disease.

So with that in mind, some components that we would like to propose for successful education programs based upon our experience with these two programs, and that is, there is a value in patient input in the development of the programs. They should promote the patient empowerment. And be aligned with evidence based practices and encourage family participation.

But I think here we get some of the points that I think I may have to uniquely offer this afternoon. And that is that our programs are designed so that they do not drive patients to a specific treatment and-or provider. And we would recommend that that be a fundamental principle in the implementation of this Medicare benefit.

And also that the educators should be well versed in all aspects of every

treatment modality. And that all modalities should be given equal time in all presentations, and equal space in all written materials. And that all pros and cons for each modality should be identified and explained.

To recap some of the earlier discussion, the best, we believe that the face-to-face is the best modality for the educational component. But that there should be -- And that group sessions are invaluable because of the peer-to-peer interaction. But also that individual opportunities should be provided for confidential discussion.

Once again, here is something that I think that hasn't been emphasized enough this afternoon, and that is the need for standardized content. First of all, the imperative for standardized content is to assure the comprehensiveness, but also it will allow for portability.

And by that I mean that a patient

could attend one class with one provider, and then another class with another provider, should they leave the community, move to another part of the country permanently or temporarily. So that they can take up again where they left off.

There's been a lot of discussion about settings, so I won't repeat that. But, and also to suggest that there should be an opportunity to reinforce patient education over time through repetitive learning opportunities.

And also an opportunity or a mechanism for evaluation and documentation of successful patient participation, as well as the relationship between the education program and health outcomes.

So in conclusion, we would urge that the when the regulations are complete for this new benefit, that the benefit will empower patients and families. Instill a sense of hope and include recognition of some

of the best practices, including a standardized and consistent messaging, scientific based for the education materials, that the program be comprehensive and balanced, that the faculty be unbiased and well versed, and that there be an evaluation component.

Thank you.

DR. POWE: Thank you, Dolph. And next we have Karen Basinger.

MS. BASINGER: I would like to introduce myself. I'm Karen Basinger, I'm a member of the Renal Practice Group of the American Dietetic Association. And I would like to thank AHRQ for the opportunity to present today.

Initially when we had this discussion, and I talked to several of my peers, but one thing that we came up with is initially we have to go back to our nephrologist. Because it is tantamount for better patient outcomes.

If we leave out the nephrologist, we're not going to get the referrals. And they're very much part of this education process.

This being said, the patient also needs to be an active participant in CKD education to comprehend the illness and the diagnosis and the treatment regimen.

The primary criterion of extreme importance would be inclusion of qualified practitioners. And when we talk about qualified practitioners, we are talking about those that are experienced in renal.

I can't tell you how many times that I've gotten calls from diabetes educators thinking they can train somebody on a renal diabetic diet or talk about renal disease. This has to be specific to the renal population.

And you don't want to self-refer out to a renal educator, they want to do it themselves for that valuable time for diabetes

education.

There's a point where we lean together, but there's also a point where separately, at this point, we work much better. So we need to consider that as well.

It is imperative in the education of a CKD patient a practitioner who has no renal background cannot truly provide the necessary education, which also includes comorbidities, and other variables.

Again, our diabetes peers think they can handle it all. But they can't. And a lot of these people that come to us with diabetes don't want to go back to these diabetes educators because they never, they deal with classes, they don't develop an interpersonal relationship. And they figure, you know, I didn't listen to them, I got this far, big deal.

So they don't really spend the time that these people need. And the educational level needs to be taken to a next level. Not

to revert back to the diabetes educator.

The other component that is missing is that MNT, whether it's for diabetes or for pre-renal, this is a benefit that has been under-utilized in all disciplines. And the more you involve them with dietary interventions, the better the results. And it is imperative that this benefit is utilized better than what it is.

In my numerous years of experience, the best outcomes are those derived from individual counseling along with the education, not a class. I've had more impact, one-on-one, than in a class.

In addition with a one-on-one session, you can emphasize behavior interventions, as opposed to a class setting which cannot effectively address these changes. And it's hard to get the people to come back to meet individually with a social worker, that usually on a one-on-one session we can pull out and pull in.

It is also for me to remind you that the US Preventive Services Taskforce has conducted a systematic review of the literature and found that outcomes are achieved in patient focus, intensive intervention, in-depth behavior change. And this is the one thing that I have to say MNT does, is we deal with behavior changes.

And in the classes that I work with, for the facility that I have to deal with in several areas. We deal with behavior changes. And sometimes that is lost in classes, because you are just one.

So as a member of the Renal Practice Group of the American Dietetic Association, I would like to continue to provide education, and act as a resource for this ongoing and valuable project.

Thank you.

DR. POWE: Okay, thank you. Let me open up the floor for any additional comments.

MS. LOGAN: Hello, my name is

Dianne Logan, I'm from Fresenius Medical Care. And I thought all the panel has done an excellent job today, and this has been very fascinating.

And I agree with Karen. And looking at the Bill 152, and it talks about the qualified provider, I understand all the professions that are involved that can be reimbursed for this, and I'm fine with that.

But it doesn't really clarify whether or not it requires any nephrology education or background. Or can any physician or any nurse or any person that meets these provider qualifications, can they, using the standard information that maybe Medicare will come forth and recommend that everybody uses for these six reimbursed stages, can anybody like a podiatrist, who might be willing to use that standard information and then give that education to the patient and then get reimbursed for that education?

And so, I've been thinking about

how to ask this question, and you opened the door, and I don't know whether I'm not reading this correctly, if it was written to be broad, which is fine.

But I just really feel that if you have a cardiology issue, a GYN issue, an OB issue, a dermatology issue, you're going to go to that professional practice person, whether it be a nurse practitioner, or clinical nurse specialist, a physician assistant or a physician.

You know, and so I'm just looking for clarification on that. Is the nephrology industry going to be the ones that provide this education regardless if it's the NKF or whoever? Nephrology in practices, not the providers, I understand that. But I just am looking for clarification and feedback from anybody. That would be helpful. Thank you.

MR. CHIANCHIANO: You've co-opted my next talk.

MS. LOGAN: Sorry. I can wait.

MR. CHIANCHIANO: Because I am going to discuss a little bit about that in my next talk.

MS. LOGAN: Okay. Thank you.

DR. POWE: I think you've raised a question, I don't know what the answer is. I'm not sure anyone here can answer that question of who would be, who the qualified person, you know, or professional would be. And that, that would be up to the Secretary.

MS. LOGAN: The Secretary. My recommendation would be, that would be really the key to look at going forward, because you really want to look at patient outcomes. And people here have spoken to, that there is data saying that after six months we don't know. But everybody here it sounds like has nephrology background and experience.

And this disease is very complicated. It is not simple. It's really a family disease, it's not an individual disease. And it impacts the community. It

really impacts everybody, it impacts the Government.

So I think that is a crucial point to look at, who is the qualified person. Not the different practitioners, I understand all that. But the specialties you have. And I would highly recommend that they would be nephrology people.

Thanks.

MS. BASINGER: Let me add something else here. I think you should go back and look at the diabetes education referral data. Because the ones that are getting referred are from endocrinologists.

But I can tell you, a number, a significant number, where the primaries are not referring for diabetes education. And the first time people hear about a diabetic diet or monitoring is when they broke down and found a dietician, and asked for this one-on-one intervention. And we wind up referring them to diabetes education.

So a lot of times the primaries are not getting these people where they need to go. And that's why I really feel strongly that it has to be a renal professional.

MS. LOGAN: Maybe one follow-up. And I think with this population, what we all see, and it comes to some of the first presentations that we saw, these people, we don't find them until they end up in the emergency room.

And so if you've got a podiatrist, or you've got a dermatologist, or you've got an OB person talking about kidney disease, that's really not part of what they're doing. It's not their chief complaint. So they might be able to order a follow-up or make a referral.

But the key for this is really a continuity of care and to get these people in the system and to educate them. And it sounds like everybody's going to do that. And the fact that the Government's going to reimburse,

six sessions is I think outstanding. And it just shows that they understand now the seriousness of the disease.

But we really need to keep these people within a nephrology system, if that makes sense. Because they're going to get lost to follow-up, and then they're going to bounce around, and then they're going to end up --

That episodic event they're going to have, and they're going to have a cardiac or respiratory event, they're going to end up in an emergency room, and that's when they're going to end up on dialysis with a catheter.

And they're going to say, why didn't I know? Why didn't someone tell me?

So I think as a nephrology profession, we really need to look at this and work with Medicare. And I would highly recommend that that qualification be discussed and really be defined.

Because I think it will either have

a very effective program, or -- maybe Sue would be effective, but I think everybody else is so busy in healthcare, they're all going to be dealing with their chief complaints and their specialties and what they need to do to provide care.

DR. POWE: I guess that's as it's now left open, I guess it will be whichever provider can get to the patient first when their eGFR is 29.

MR. CHIANCHIANO: I think we may also learn something from the MNT benefit that Karen was talking about. And unfortunately it is terribly under-utilized.

The Congressional budget office originally estimated that it would cost Medicare about 60 million dollars a year. And Medicare's billings, payments, are running around five million dollars a year.

And one of the issues, quite frankly, is that it's almost impossible to find anything about medical nutrition therapy

on the CMS website. So if a beneficiary doesn't know how to ask for it or how to access this service, then it's not likely to be utilized.

MS. SALSTROM: Hi, Tonya Salstrom with Dialysis Patient Citizens. I think a very important point was just raised, and that is, this legislation also talks about public awareness campaigns. And that public awareness is to help educate the medical community. And I would extrapolate from that, primary care physicians as well, to run tests for the disease, but then make the appropriate referrals and start the discussion for education for kidney disease.

So I just wanted to throw that out there. We've been focusing on the six sessions, but there's also that public awareness component where we can also educate the medical community.

DR. POWE: Thank you.

MS. CARY: I am Sue Cary from the

American Nephrology Nurses' Association. Just a comment to what Karen had said, that, actually I'm a nurse practitioner in Baton Rouge, Louisiana. And I have a chronic kidney disease clinic. But I was approached by internal medicine doctors when I work with their diabetic educator and their diabetic nutritionist to talk, and, you know, for her to do, like, education of comorbidities.

So we had faith that it's out there, it's real. But I told them about this legislation and the internal medicine docs were excited about that.

One other thing I wanted to mention. I was looking, and I found in the literature, an article entitled the importance of CKD clinics. And some of the education is obviously dealing with a lot of nurse practitioners trying to decide, this was a couple years ago, what we're going to do as far as education or CKD clinics.

And one thing you mentioned is

scientific based, and some standardization of the education. I think that would be very helpful.

And one thing that this article had said that I thought was really great about the education of anemia management, hypertension, secondary hyperparathyroidism, lipid management, access placement, renal replacement therapy.

And then, they called it a one-stop shop. Basically these are clinics that were run by advanced practice nurses, and they were the go-to person who coordinated then with the dietician, because that's very important, the multi-disciplinary approach is very important.

Making sure the patient did get to the dietician. Making sure they did get to the social worker. So it's one person that coordinated all of this to make sure the patient did receive the benefit of all the multi-disciplinary approach.

Thank you.

MS. ORTIZ: Hi, Brenda Ortiz from TMF Health Quality Institute. We're one of the quality improvement organizations working on the issue that someone just talked about, in terms of working with primary care physicians and the early referral, or appropriate referral to a nephrologist.

And, you know, we know that that's where we need to go. The challenge, at least in our state, but I think this is also nationally, is that there just aren't enough nephrologists. And so, we are going to be challenged with that in this topic as well, if we're thinking that nephrologists or even the renal dieticians would be the appropriate people to deliver this program.

I agree with that, but I think in some areas we're going to be very limited in terms of how many professionals we will find in our communities to deliver that.

So that is a concern, so it's very real in our state where we're challenged with

that.

The other issue is that for many of our primary care physicians, you're right, they're not aware of the programs that Medicare covers, with medical nutrition therapy, and even diabetes self management programs.

Some of them may be aware of the coverage, but they don't know what programs to refer patients to. So, a lot of the work we've done over the past few years is linking the PCPs to information sources in their communities. And that seems like they would know what's in their community, but the reality is they don't, a lot of times.

DR. POWE: Thank you. Let me ask Dolph a question. Is standardization compatible with individualization?

MR. CHIANCHIANO: Well I think the standardization should be that certain specific number of topics have to be covered in the course of the educational services.

Then you can customize the way that the information is delivered to the specific needs of the particular patient.

But even if the patient is convinced, for instance, that they are only interested in a transplant, we know that they should also have the opportunity to understand the different types of dialysis treatment, peritoneal dialysis treatment.

So that, as will probably be the case, they may not eventually receive a transplant or they may have a transplant which fails, they will be prepared to deal with some of the other options.

DR. HOSTETTER: Dolph, you mentioned -- Tom Hostetter, ASN. You mentioned evaluation as something that ought to be on the list of things, evaluating whether this works.

Either you or other people, what would you envision as a way of evaluating what the societal benefit, or economic benefit of

this CMS benefit would be?

MR. CHIANCHIANO: Well certainly, since the legislation talks about delaying progression, that would be one parameter to look at.

But another one certainly, the type of vascular access that a patient has at the initiation of dialysis.

Something that Beth would probably say, whether or not they remain employed or whether they have undergone rehabilitation training.

Their general health status would also be a way of evaluating.

But as I said, the one that Missouri Kidney Program had, and the People Like Us Live Program has used, is evaluating coping. So that would also be an issue that should be considered.

MS. WASHINGTON: My name is Debra Washington, I'm with the National Kidney Foundation, with the Transaction Executive

Committee. I am a kidney recipient as of November 29th, it's been 11 years.

We do have the advantage of having volunteers nationwide, so we have patients who can help. I can walk into a dialysis center or to a transplant center, and I can show the patient my fistula. I can show them my incision. I can talk to them about why I chose hemodialysis versus peritoneal dialysis.

So keep in mind, they do got a lot of resources out there who are willing to help. Okay?

DR. POWE: Okay, I see no more commentors. I want to thank --

MR. RETTIG: Dick Rettig, RAND. I have a question for really everyone here, and that is, how important is it for a patient to know their estimated GFR? If you go back to the start on the clinical diagnostic criteria for stages III and forward, GFR is the control.

Is it the same as knowing high

blood pressure? Is it the same as knowing cholesterol levels? Is it the same as knowing glucose levels?

And if that's the case, then what obligation, or what advocacy should be made to Medicare, Medicaid, private health insurers, large employers, to reimburse the, under some circumstances, under appropriate circumstances, the estimation of GFR?

So I would welcome any discussion on that point.

MS. WITTEN: Well I've kind of wondered why, when they came out with the Welcome to Medicare benefit, why that wasn't included in that. You know, I've often said, you know, we have all these people, it's a pretty expensive program, seems like that would be a very simple thing to add to the Welcome to Medicare.

MR. CHIANCHIANO: And interestingly enough, Welcome to Medicare includes referral for MNT, but you can't refer for MNT without a

GFR.

DR. HOSTETTER: Tom Hostetter, ASN. I maybe can correct this, but I think about 40 percent of labs report this now. And probably a far higher percentage of patients get it. Because the two largest commercial labs, Quest and LabCorp, provide it. It's provided for free, so that it's out there.

I mean, it obviously has the difference between say, from blood pressure or blood sugar, is that we act on it to try to lower blood pressure or blood sugar, but we're really trying to tell the patient, well it's okay if you keep this at the same level.

So, there's a very different kind of message that's delivered. But I think over the last five or six years, with a lot of people's help, the reporting of that has become pretty close to routine around the country.

Whether the patients know what their values are is another issue.

DR. POWE: I think it's interesting that, you know, if you look at where blood pressure was, cholesterol, glucose was, 15, 20 years ago, maybe that's where your eGFR measurement is now.

MS. COMPTON: And I think that because we have those questions, that might be another argument, that a renal professional is the one who needs to discuss those with the patient. Because an eGFR of, you know, 17 or 18 milliliters per minute in my 85 year old isn't going to mean to me what that is going to mean in a 30 year old that comes to me.

So, again, getting back to who is going to provide this education, even if it's a renal professional, they should meet certain criteria as well, whether they are in nephrology or not. Or whether they are in nephrology, because those are the exact issues they would have to be kind of zeroed in, that a renal professional needs to provide for the patient. What it means to that person.

DR. POWE: Thanks. Why don't we move along. I would ask our next commenters to come forward for question five.

So question five is, what are the existing kidney disease education resources that are publicly available? And in addition to these resources, we're asked to provide information regarding the sponsorship or funding provided to produce existing education programs.

And our first commenter will be Alice McCall.

MS. McCALL: Good afternoon and thank you. My name is Alice McCall. I am a Board Member, National Board Member of the American Association of Kidney Patients, a transplant recipient, and also an RN.

And our comment today is, the American Association of Kidney Patients, in case you don't know us, has been providing education resources for patients since 1969.

The organization is governed by a

board of directors composing of dialysis patients, transplant recipients, CKD patients, healthcare professionals, and members of the public concerned with kidney disease.

AAKP exists to serving the needs, interests, and welfare of all kidney patients and their families. Its purpose is to help patients and their families cope with the physical, emotional, and social impact of kidney disease, thereby enabling them to resume productive and satisfying lives.

AAKP reaches one million patients a year with its variety of educational material. We make education available through print, web, seminar, telephone. Information must be provided in a format in which the patient wants to receive it. And we're speaking there of customizing and personalizing, therefore to try to accommodate the needs of all patients.

One of AAKP's many focuses is that of CKD education. AAKP Kidney Beginnings is an educational series, was started about eight

years ago, and includes a live seminar, electronic newsletter.

AAKP believes that offering both a written and live educational program gives kidney patients the best opportunity to educate themselves and their families, enabling them to lead a happier, and healthier life.

The educated patient is better able to become an active participant in the planning, managing, of treatment. Its online personal health record, AAKPMyHelp, helps track medication, lab, and physician care.

In addition to being a resource tool for monitoring progress, it also provides education so patients can have understanding of what their lab values mean.

The benefit to this personal health record is, as if a patient transitions from ESRD, the information stored as CKD information remains, but new lab values entered will be specific for ESRD.

The AAKP Patient Plan was developed with stage IV patient in mind. When patients first hear the words kidney disease, it can be a lot to absorb. Then to leave the doctor's office with an armful load of education materials is overwhelming to say the least.

The Patient Plan was created to categorize the journey of kidney disease into four phases. The first and second phases, diagnosis to treatment choices and access and initiation, are ideal resources for CKD patients. It allows the patient to take in information in a more controlled fashion. And the patient decides when he is ready to receive the next phase of materials.

It also gives control back to the patient, because when you are coping with a chronic illness, it's easy to feel as though you are losing control. You rely on so many other resources for information, doctors, nurses, et cetera. It's helpful, therapeutic, to have a sense of being in the driver's seat.

And the Patient Plan provides that.

As a patient who has benefit from the services of AAKP, it is a peer-to-peer education that separates AAKP from many educational resources. When you're experiencing a chronic disease, nothing is more powerful than receiving education support from a peer.

When organizing the ESRD option education, we would recommend a conservative managed approach as well as ensure advanced directives are included in that information. When making decisions about healthcare, it's important that all information is made available, and that patients can decide when it's appropriate for his next stage of needs.

AAKP maintains AAKP resources are available directly to patients through generous sponsorships. The organization is willing to discuss options for alternate distribution resources.

And thank you so much for having me

here today.

DR. POWE: Thank you.

DR. HOSTETTER: Good afternoon, I'm Tom Hofstetter. I'm representing the American Society of Nephrology. I actually work in the renal division at Albert Einstein College of Medicine in the Bronx, New York.

The ASN is a large professional society of about 11,000 members. And so almost all of the 7,000 or so board certified adult nephrologists in the country are members of it. In addition, a number of basic scientists, pediatric nephrologists, pathologists, and foreign non-US nephrologists are members.

We are not a patient or a nursing or a dietetic informed membership. But one of the reasons I'm here is to tell you that the ASN is quite willing to work with the development of whatever materials are available.

And we don't really have a direct,

sort of, dog in the fight, because we haven't been a direct patient kind of organization, even though our members are the ones who for the large part take care of the patients.

So I'm really here in sort of a role as my former life. I worked up until three years ago in the National Kidney Disease Education Program, which Eileen Newman works in now.

And so, I'm really here to remind you that there are some really, I think, high quality sets of materials and resources and thinking available right now in the National Institutes of Health.

The first, the National Kidney Disease Education Program, this sort of screenshot comes from what you get when you put NKDEP into Google, and I urge you all to go to that site.

The program was really envisioned as, much like the high blood pressure, cholesterol education programs which were in

another institute, and that is to bring the science of NIH to some kind of practical public use.

And so, two groups were targeted. People at risk for kidney disease, and their providers. And to get at these people earlier, they were really primary care providers, not nephrologists who we targeted and who NKDEP targets now.

And that's sort of showing, there are things for the public, patients, for health professionals. Again, nephrologists but primarily primary care providers and other groups like laboratory professionals in order to improve the reporting of creatinine and in turn the accuracy of estimated GFR.

There's just loads of material on this website which have been I think very thoroughly vetted, both for their reading levels as well as for their scientific accuracy, and their efficacy at least as judged by things like focus groups.

These are just some examples. This is more for the professionals, two of the major tests explaining in terms that the primary care providers can understand, the urine albumin to creatinine ratio, one of the key indicators of chronic kidney disease, and the use of the estimated GFR. Again, from the website.

These are, it says, materials for primary care providers, but this is material that's actually provided to patients. And this sort of relates to something Dick Rettig said, that we got to simplify the way of looking at GFR along this sort of speedometer range, so any number of ways of kind of conceiving of it. But again, these have been things that seem to register with patients.

There are sort of suggested, sort of talking points for providers that could be used. Things like talking about how kidney functions when it works, the importance of testing and the simplicity of testing. And I

think we would urge simplicity as a key element in any education program.

But to describe that CKD tends to be progressive, although there's therapy, and fourthly that there are end-stage measures to be taken.

In addition to this program, which started about seven or eight years ago, and I think I can say this without tooting my own horn, that it's done even better since I've left in the last three years. I think it's a big resource and it has a track record in developing some of these materials in an unbiased and scientific fashion.

But even predating this program, is a resource which I find most people aren't aware of, and that's called the National Kidney and Urologic Diseases Information Clearinghouse, also run by the NIDDK in NIH.

And this is another screenshot. It shows you beginning A to Z of the kinds of materials that again have been scientifically

scrutinized, but also developed to be, having the appropriate reading level and usefulness to the usual population.

And this list begins with acidosis, moves down through bed-wetting, down to blood pressure, and that's only A through B. So there are multiple publications that are available, that are essentially for free. In large bulk I think they charge for the shipping, but not much else that are again fairly scientifically based and readable.

If you really hone down on it and look at what they have, for example, for the methods of treatment of kidney failure, you could see that choosing the particular type of therapy is in both English and Spanish. Hemodialysis, peritoneal dialysis, and if you scroll on down you'd see transplantation etcetera.

So this clearinghouse, which is sort of a parallel just information source, which is not highly marketed, but highly

available through the NIH website, that I think would be a terrific basis for at least some of the things that are being contemplated here.

So I'll stop and summarize to say that the National Institute of Diabetes, Digestive and Kidney Diseases, at NIH, has well vetted that is scientifically reliable and unbiased in materials for patients and providers. That is a benefit of working with the taxpayers' dollars rather than with industry dollars, that the materials are less likely to come under that sort of spotlight.

I would say, returning to my role as ASN representative here, that we would be happy to help with whatever development does occur. And since, you know, we don't have a particular set of these materials of our own, we hope we could do it in a relatively unbiased way ourselves.

Thanks for asking us to speak.

DR. POWE: Thank you. Let me open

this up to further comments.

MS. KITSEN: Jenny Kitsen, Network of New England. I just wanted to capitalize on a couple of comments that Alice said there, because I'm afraid we might have drifted by it.

The idea of conservative treatment, that no treatment is an acceptable treatment. I think we may not be thinking about in terms of this context, of the educational modules that we're thinking about.

But we may want to revisit that and put it on the list of something to be considered, because I think patients are very reluctant in the process of moving towards that treatment to even raise the subject.

So there needs to be some way of introducing it in a non-threatening way, and trying to draw it out. As well as the idea of what advanced directives are all about.

I don't think that it's beyond the scope of early education to somehow figure out

a way to make sure that we incorporate these topics in this educational modalities that we're topic about, or modules.

So I thank you for raising it.

MS. McCALL: And you're right, thank you for that comment.

We did put it in there because we know it's a major issue, but as you mentioned it kind of slipped by. But those are pretty major issues, exactly right.

MS. KITSEN: And there is already a website and a national coalition of parties that are belonging to a coalition for end of life care, so there are some resources that are already available, you know, that might assist in this discussion and consideration too.

MS. McCALL: Thank you for your question.

MS. RUSSELL: Jennifer Russell, American Kidney Fund. A couple of things, just to add to, and in terms of resources.

The American Kidney Fund has a help line that's staffed by health educators, that anyone can call into and ask questions about CKD, ESRD, general health questions, understanding lab results. It's available in English and Spanish. As well, we have a brochure series.

And just to piggyback on some of the things that were mentioned in terms of resources. I think we need to bring back to the beginning of the discussion where we talked about cultural appropriateness and thinking about that. Just because a piece of literature is translated doesn't mean it's culturally appropriate.

And then finally, the principles of health literacy and looking at writing things, using plain language principles, so that everyone can understand, and whereat that, everyone can really, truly comprehend what you're saying, not based on any kind of education level or what they're background may

be. It's just clear communication that anyone can understand.

MR. CHIANCHIANO: Dolph Chianchiano, National Kidney Foundation. The National Kidney Foundation is one of 30 members of something called the Kidney Care Partners Coalition. And the Kidney Care Partners Coalition has a workgroup that is specifically charged with making recommendations to CMS on the implementation of the Section 152(b) of MIPPA.

And as part of that task, the workgroup is going to assemble at least a catalog of all of the kinds of programs that might be useful as precedents for this new education service. And we will be happy to provide that to CMS and AHRQ staff.

MS. SINGER: I would just add that the guideline that I had mentioned earlier, the Appropriate Patient Preparation for Renal Replacement Therapy, an outgrowth of that guideline was an advanced CKD patient

management toolkit that we created for stage IV, stage V patients.

This is Dale Singer from RPA.

And that toolkit is actually right now being field tested by ten nephrology practices across the United States to look at how patient outcomes improved in specific areas that are identified in the guideline.

And we're actually using, again, the Duke Clinical Research Group to help us implement that study.

And we're also making that toolkit available to the ten QIOs that have the contracts from CMS to implement the demonstration project in CKD.

MS. WITTEN: Beth Witten, again. This time I'm talking for Medical Education Institute. Medical Education Institute also has Kidney School, which is an interactive web-based program. People talk about people not having access to the internet, but actually more people do have access to the

internet than people believe, because it's available in libraries, it's available through family members or friends.

So, there's 16 topics that are up there right now that people could access 24-7. If they work through it interactively they get an action plan at the end that encourages them to talk to their doctor, do a variety of things, based on how they answered questions throughout the module.

In addition, Medical Education Institute also has a website called Home Dialysis Central, and it has a fact sheet to help patients and their professionals evaluate somebody's candidacy for home dialysis therapy.

Because frequently people underestimate patients' ability to do home dialysis. And that dispels a lot of the myths about home dialysis. And there were a lot of professionals that helped to create that document.

So, it's done in color coding so that it's easy to figure out where somebody might fall. And that's something that could be used in the discussion with patients.

DR. POWE: Do we have any more comments? Yes.

MR. SWITZER: Hi, I'm Dave Switzer from the PKD Foundation. We've been talking a lot about very general kidney issues as a whole.

But there's a lot of organizations like ours that are out there that are focused specifically on one condition, such as PKD. But PKD is a CKD, and for roughly 50 to 60 percent of the people with PKD chronic kidney disease, ESRD is where they're headed with that.

So, there's lots of other groups that are maybe a little bit more niched, if you want to call it that. But we also look to provide information along those lines as well.

So there are a number of other

groups that might not potentially be as broad based, but yet, who are trying to provide the education for a specific population of the CKD community.

MR. RETTIG: Dick Rettig, RAND. I don't know if this fits in this question or not, but I'm going to launch it anyhow.

I was once on the board of MEI, and I talked to Beth a moment ago about this. And that is, MEI was concerned with patient rehabilitation. How do you get at that?

So the Board devised a system of applications from individual dialysis programs, and awarding of prizes annually. And think about it for a moment. This is a very low cost thing. Dolph described the workgroup, and they're going to generate some recommendations on content I take it, and standards and so on and so forth.

But then, one could very easily invite from the renal community, applications for best CKD education prize of the year. You

could do one in each region. You could do one in each network. You could have some sort Superbowl of the thing.

What's remarkable is people really move. they act because of the possibility of recognition for what they're doing and I just offer it as a consideration.

DR. POWE: Thank you. Seeing no more commentors. Let's move to question six.

So, question six really is an offshoot of this previous one. Are there organizations in existence that certify the content of the education services that are currently publicly available? And what is their sponsorship, or the funding for the certification entities?

And we have Dolph, who was here before, Beth, who was here before again, to comment.

MR. CHIANCHIANO: Thanks again. Unfortunately, the woman from Fresenius had to leave, but I'm going to at least in part

address her question.

And I should also state that I would be interested if anyone from CMS has any different take on the issues that I'm going to approach.

But I thought I would start with some legislative history. And section 152(b) of MIPPA, as you know, creates this new benefit.

Congress considered a number of alternatives to assure the quality of the education services that would be provided to Medicare beneficiaries with stage IV kidney disease.

In the Kidney Disease Education Benefits Act, and the Kidney Care Quality in Education Act, which were ultimately incorporated in MIPPA, there was a provision whereby the Secretary would have been required to develop requirements related to the experience and qualifications for the personnel furnishing the education services.

This was the point of the question from the Fresenius representative.

So obviously this was one approach that Congress had considered during the unfolding of the history of this legislation.

However, that provision, that was in the earlier bills, does not appear in the Medicare Improvement for Patients and Providers Act. Instead, there's an entirely different provision in MIPPA, and that's the provision that we were asked to address in number six.

The MIPPA provision states that the Secretary shall set standards for the content of the information provided under this new benefit. Rather than the qualifications of the educators.

One could argue that there probably should be a regulatory framework that would cover both the qualifications of the educators and the content of the educational program. And I don't know whether that is being

entertained by CMS or not. But I thought I should put that in context when we're talking about certification.

In contrast to the language of that you see and that I just referred to in MIPPA, the Balanced Budget Act of 1997, which created the Diabetes Self Management Training Benefit, and I think Beth is going to talk a little bit more about DSMT, that legislation specifically stated that section 4105, that a physician or entity meets the quality standards described in this paragraph if the physician or individual or entity is recognized by an organization that represents individuals with diabetes as meeting standards for furnishing the services.

So there's no provision at all like that in MIPPA. But that doesn't mean that CMS cannot create a similar requirement on a regulatory basis. But this is the statutory basis for the accreditation of diabetes self management training programs.

Now the concern about accreditation has two faces. Accreditation, theoretically at least, provides some kind of guarantee of the quality of the individual educator or the individual program content.

On the other hand, by requiring accreditation, you are potentially decreasing the number of entities or individuals who could provide the service and therefore reducing access to the service.

So that, in the final rule for diabetes self management training, the Healthcare Financing Administration, now CMS, stated that the American Diabetes Association would probably apply, and would be quickly approved, as an accrediting agency, which it has, it did.

There are two deemed organizations by CMS, that's ADA and the Indian Health Service.

However, HCFA then went on to say, we recognize that some small entities may find

that the American Diabetes Association's requirements would be a burden, and thereby suggesting that there might be a possibility of impaired access.

The agency went on to predict that there would be 819 approved entities, and that the number will increase about a hundred per year. Actually, the accreditation process has been somewhat successful, because we understand 2,921 diabetes self management training programs that have been approved by and recognized by the American Diabetic Association.

So, to wrap up, there is no comparable certification body for kidney disease patient education at the present time. The National Kidney Foundation's Kidney Learning System, however, does have an editorial board, which is responsible for certifying that our own educational programs are accurate, unbiased, and consistent with the clinical practice guidelines of the

National Kidney Foundation and peer organizations.

And that body has responsibility for overseeing all of our education resources development. It approves and reviews the content of all of our educational materials and facilitates pilot testing of those materials. It's multi-disciplinary, multi-specialty, including primary care practitioners, kidney specialists, endocrinologists, cardiologists, other specialists, as well as patients and family members.

There are 71 members of the National Kidney Foundation Kidney Learning System Editorial Board.

Thank you.

DR. POWE: Thank you. And Beth Witten, next.

MS. WITTEN: And last, but certainly not least.

Beth Witten again. I am

representing Medical Education on this one.

Okay, so, those are my disclosures again. I work with the National Kidney Foundation, and I consult with both Missouri Kidney Program and Medical Education Institute.

One of the things that the MIPPA law did was, it provided great value in certifying people who provided education, I believe.

I believe that we've all had good and bad education from the healthcare professionals that we've visited with. So even though the law doesn't say that there needs to be some kind of qualifications of health personnel, I believe that it's very important for there to be some kind of qualifications.

As I said earlier in my first presentation, patients that come to our Missouri Kidney Program classes miss over half of the questions. And they're pretty easy

questions, 24 questions. So they're not getting enough education.

Professionals, I believe, need to meet certain minimal education, and nephrology experience requirements, to be certified to provide education. That would also include licensure, or certification under state laws and their particular location or state regulations.

And they need to have sufficient education on the topics related to the CKD curriculum, and also adult learning theory.

I believe that they need to pass a standardized exam with questions that cover those topics, and that there needs to be recertification as a CKD educator, at least every two years. And there has to be continuing education as part of that.

Maybe CMS, if this were undertaken, could list the qualified CKD educators on their website, so that primary care physicians could refer to them.

So far as the qualifications, the nephrologist, the nurse with the CNN, dietician and the masters prepared social worker, are all appropriate people to be involved in the education.

One of the questions that I have about the law is it says that it needs to be done by certain people. Could it be done by those people with other folks involved in that education? So, could it be billed under the physician's provider number, and even be provided by those other people in the physician's office, if they were employed by the physician? That would be a question that I would ask.

So, so far as the diabetes self management training, I thought that because of all the money that's gone into diabetes and research and education, we needed to really look at that benefit. It's been in existence since 1997, as Dolph said, the American Diabetes Association and the Indian Health

Service are approved accrediting organizations.

Neither of these organizations offers the education themselves, so it's not like there's any kind of conflict of interest that you could find from an organization that does educate.

And there are, like Dolph said, about 3,000 certified DSME or T programs in the United States. By certifying education you're going to define the content, you're going to assure that the educator meets certain minimal criteria.

And you're going to be basing the information hopefully on research, not just on what people believe and their biases.

It's also going to also further the education goals so that people will be empowered and encouraged to do self management.

And it also will assure that CKD patients receive at least as good education as

patients with diabetes.

And one of the things that I looked up on the American Association of Diabetes Educators website, was how many people had sought diabetes education. And they had some statistics and a fact sheet that said, 54 percent of patients with diabetes had self reported seeing an educator.

But they said that only one percent of those diabetics that had Medicare had gotten diabetes self management training in the years of 2004 and 2005. So the question that I would ask is, why is this benefit so under-utilized among Medicare patients? Is it something related to how the people are referred? Is it something related to the reimbursement that they're getting?

But that's something to consider when setting up this benefit, so that people do have access.

So, facts alone don't change behavior. I think we all know that.

Fundamental goal of this educational benefit is to empower patients to make good healthcare decisions, and to be actively involved in their care. What we want is health behavior change. And how you get to health behavior change is by impacting patients motivation.

One of the things that medical education believes is that this can be done through self determination theory, which has certain goals. And that is to increase patient's autonomy, which is the sense that you are the captain of your own ship.

To improve competency or self efficacy, the feeling that you can achieve what you want to achieve.

And the sense of relatedness, which is the sense that you can get support from your family, your friends, your community. Perhaps from a group education class. From your healthcare team.

Beyond that, there are good data on

the value of behavioral and psycho-social strategies, so I don't think that you can leave out the social worker. I would say that to anyone.

And the group based education to support these three critical psycho-social needs will improve outcomes.

There is a literature basis for effective chronic kidney disease education, and this slide just shows a few of the research studies that have been performed on the benefits of that.

So patients' education interest varies over time. We talked about this benefit being for people that are in the GFR less than 30 range. But people that are in that higher range of GFR want to know, how can I prevent kidney failure? How can I keep my kidneys working as long as possible? What are the things that I can do to prevent comorbidities?

We need to tell them about things

to do so far as preventing or avoiding nephrotoxic agents. How to live a good life with kidney disease. Things to do to take more responsibility for your health. How to keep working. How to report the symptoms to your doctor so that they can take care of the things that might make you have to quit your job.

And once they hit the GFR of 60 or below, then it's like, what's the impact of choosing a particular treatment on your lifestyle? How is that going to affect your finances? How is it going to affect your job? How is it going to affect what you eat, what you drink, your sexuality, your fertility, hospital days, mortality risk?

People have talked about unbiased education, and I hope that what people are talking about is, don't put your mind-set on patients, but look at what the patient needs for his or her lifestyle.

And we need to be educating people

about the survival statistics of different treatment options too. I mean, unbiased education would have us believe that every treatment is the same. And every treatment is not the same.

Patients need to learn about all the different treatment options. The in-center treatment but also all the home dialysis options. The option to do nocturnal in-center, or nocturnal or daily at home.

And then, transplant. Donor transplants. Living donor transplants. Other options when you don't have a potential living donor, so far as paired donor exchange.

And some of the newer modalities. Kidney pancreas transplants for those that are type I diabetics. Avoiding complications. Activity limitations related to transplant, or related to different modalities. Medications, costs and coverage, it goes on and on. And obviously, coping.

So, one of the things I think with

the diabetes education program that's made it burdensome is that you got to collect 12 months worth of data before you can apply to be a provider.

So my suggestion would be to collect six months worth of data on such things as these that I listed here that are known contributors to progression of kidney disease. I'm sure that there are many others.

One of the common questions that patients do ask when they find out they have chronic kidney disease is, what can I do to avoid dialysis? Because they've all heard about dialysis, and the media doesn't portray it very well.

So sharing information about these topics and encouraging patients at every visit to share their progress and share what setbacks they've had is another way that we can help them postpone kidney failure.

And this is the way I'm going to end. This is a quote off the dialysis support

listserv. There's so much more money in diabetes education, so much more research on the value of education in improving outcomes, it seems really silly for us to start all over again. We might as well take advantage of what is out there and where they've evolved to.

The kidney community has accepted Medicare monies for decades now to treat a costly disease, and we promised that we were going to deliver on helping patients to work. We've not done a very good job with that.

But I think that if we can provide chronic kidney disease education in a way that will help more patients keep their jobs, then we can return them to productive living, as well as keeping them healthier for longer. And hopefully saving money in Medicare in the process.

And I want to thank you for the opportunity to present Medical Education's rationale for standardizing and certifying

education programs and educators.

Thank you.

DR. POWE: Thank you. Let's open this question up for further comments.

MS. SINGER: Dale Singer, RPA. In our written comments, we're on record as being opposed to certification. You know, the value of the program and standardization would be in the content. And when you look at models, I think there are good things to look at with models, and there are things you need to be careful about looking at, with models.

If we were to create an entire industry around certification of this education benefit, we could be asking for a lot more trouble than we know. And I think we should just be very careful.

You know, nephrologists are already certified to deliver CKD care. And nurse practitioners working in those practices as well as physician assistants working in nephrology practices are certified to provide

that care as well.

So, I think we really need to really think this through. And think about access, think about reimbursement.

One of the things Beth mentioned was why the diabetes education benefit was not being utilized by Medicare beneficiaries to the degree it should be. And reimbursement does guide practice. And I think that we are going to have to carefully structure the reimbursement for this benefit to be sure that it's properly utilized for the benefit of the patients.

MS. WILLIAMS: Hi, Deb Williams, Baxter Healthcare. One thing that hasn't been brought up today in talking about certification and who are the entities who do it, is the provision a lot to do with rural hospitals.

It's a really great thing in that there's not many nephrologists in Montana. And, you know, primary care physicians in

rural areas can often be very overwhelmed with their patient base.

It's not clear to me how it's going to work. And I hope -- I just like to ask, I'm sorry I'm going to use this as a venue, but people reach out to the rural hospital and the hospital community to help them think about how this can be delivered in their setting, because the law does provide for it.

DR. POWE: Let me ask a question. You mentioned, Beth, you mentioned that there's 50 percent of patients, almost 50 percent of patients have diabetes and CKD.

And so, if there was certification, wouldn't it be great if the patient could take advantage of having someone who is certified in both areas?

So my question is, do you think there are professionals who would want to get certified in both those areas?

MS. WITTEN: Well I think it comes back to money to a big degree. Because there

are people that currently are CDEs that have had nursing training, and perhaps worked in nursing.

One of my real good friends moved from home training nurse to CDE.

I think that the environment has to be lucrative enough, and that's probably a terrible word to use. But it has to be, has to reimburse enough so that the people will want to do that.

But I think that would be great if that was available, because then you'd have the people that would have the nephrology background as well as the diabetes background.

And if I were -- if what I suggested came to be, then there would need to be some experience requirement. And they would have to pass a test.

MS. BASINGER: Karen Basinger, a member of the Renal Practice Group for the American Dietetic Association.

In regards to the question about

diabetes educator and a renal practitioner, it's been addressed numerous times in the nutrition area.

But the problem is a lot of these people that are out there, that are searching for these services, they are just not getting the message. And I don't know whether it's how the diabetes education programs are set up. But they're not getting those messages, and that's why they're coming to us.

They're coming to kidney failure much quicker because they aren't getting the messages. They may only go for one session, decide they don't like that educator, not realizing there's a rest of a team to come on and present this topic. But if they don't like the first presenter, they don't come back.

And if you're going to make them joint between diabetes and renal, I don't see it's going to work, because the message isn't going to get there. It's about finding the

right provider to give the right message.

And it's not so much being certified in everything, but getting that right message out.

MS. WITTEN: Well the other thing I think that you kind of bring up, or that strikes in my mind, is that it's very hard, like Dolph said, to find anything, I did find it last night, medical nutrition therapy on the website. And then to try to find a dietician that does medical nutrition therapy is another roadblock.

So there needs to be better promotion, marketing, I don't know what the term is, of the people that do these services so that people can access it.

Like, I know that I can go onto the AMA website and go to their doctor finder, and I can find a doctor. You know, it needs to be that easy, so that people can do that.

The other thing is trying to find out what the criteria are for medical

nutrition therapy from the renal standpoint, is not easy to find. I did finally find it last night.

DR. HOSTETTER: Just a couple points of information. Did I understand right that the certification for the diabetes self management, took 12 months to get that for a person?

MS. WITTEN: What they have to do is they have to --

DR. HOSTETTER: If I started today, it'd be 12 months before I could get certified?

MS. WITTEN: They have to collect outcome data for 12 months before the program can apply.

DR. HOSTETTER: What's the cost? What does the ADA collect for my certificate for being a --

MS. WITTEN: Should have looked that up, I didn't look that up.

DR. HOSTETTER: Do you have a

guess?

MS. WITTEN: I can find it and let them know so that it can go into the report.

DR. HOSTETTER: Thanks.

MS. WITTEN: I'd be happy to look that up.

MS. ORTIZ: I have a question on the ADA recognition. I think I remember that the certification is for the program and not so much for the staff, is that correct?

MS. WITTEN: The staff have to meet certain qualifications too. They have to have a CDE and it could be nurses and dieticians are typically the people that are involved in the diabetes education.

MS. ORTIZ: Okay. I do have one comment related to the under-utilization of the DSMT. In our state in Texas -- and this is Brenda Ortiz from TMF Health Quality Institute, the QIO in Texas.

One of the things we have found is that a lot of the programs, at least in Texas,

are offered in hospital settings. And for many patients the location matters a lot in terms of whether they come back.

We also know that the delivery of the program has a lot to do with retaining those patients, especially when we look at Hispanic, African American patients, which are our largest groups in Texas.

We find that for many groups, they prefer the group instruction versus individual one-on-one. And the reason for that is, a lot of them trust their peers more so than the medical establishment. That's one.

Two, there's a lot of myths that they don't feel comfortable talking about with the practitioner one-on-one, but they might be more comfortable in a group setting where they know that others feel the same or think the same.

And so just a comment related to that, location matters a lot in the provision of these programs, and whether people attend

or not.

And the other comment I had made earlier about PCPs knowing about resources in their community, that is an ongoing issue. We have seen that in Texas for many years now. Continues to be an issue.

So I fully support having an easy website or something that a practitioner and patient can go into and look up resources in their community.

MS. WITTEN: Well I did look at this fact sheet on the AADE website, and it talked about how initially the diabetes self management training program started in hospitals. But they have learned that they needed to expand out into the community. And so now they're doing more community education, and educating as many people out in the community as they are in the hospitals.

MS. RUSSELL: Jen Russell, AKF. I just want to reinforce the point, Beth, that I think that you mentioned.

And all the certification talk seems to focus on the content, whether the nephrology related content. But pulling back, I think we need to look at, again, are these folks trained as educators as well? And making sure that there is some understanding of adult learning principles and that sort of thing.

Perhaps it's not a certification, but some sort of CME requirement that just as ethics is required for social workers, for example. Something along those lines, because if we're going to turn clinicians into educators, they need to have a basic understanding of education theory.

MS. WITTEN: That's why I suggested on the exam that they would take, assuming that anybody thought that it was a good idea, that there would need to be some questions related to adult education theory.

DR. POWE: Okay, I want to thank our commenters, and the rest of you for those

comments.

So this is the portion of the meeting we moved into, the last and final session, which is an opportunity for you to bring forth any other issues besides these six questions that you think may help the Secretary and CMS in implementing this.

So, if you have any comments, come to the microphone.

MS. ORTIZ: One other issue that I know exists in our state, and this is Brenda Ortiz from TMF Health Quality Institute, is the issue that, for example, DSMT is covered under Medicare part B, and so there is a copayment for the patient. And we find that that can be a barrier, even though I think in some areas it's a few dollars. But that presents an issue. So, just wondering if there was any thought into how this would be paid for, if it's under part B, is there going to be a copayment for the patient?

DR. POWE: Okay, good to get for

the record. Any other comments?

That easy?

MR. CHIANCHIANO: One of the issues in the medical nutrition therapy benefit reimbursement, as I understand it, initially CMS did not allow an office practice expense for the dietician who was providing that service, and that it took a couple of years before that was recognized in the physician fee schedule.

So I guess the question here is if a nurse practitioner or a physician assistant is attempting to direct bill CMS for their service, whether they would be allowed an office practice expense?

DR. POWE: Any other comments? Are there any more comments related as you thought of the six questions?

Gotten it all out? Okay.

Well, I want to thank everyone for providing these comments for our meeting today.

Just a couple more housekeeping things. If you have any further comments, you can submit them, as I said before, to CKDEducation@cms.hhs.gov after the meeting, CMS has said it will take comments for up to the next 30 days, at least, on these issues.

Also, if you're driving today, you need to exit from the Gaither Road exit, where the parking attendant is located, rather than the other exit-entrance.

So, thank you all, thank you all for your comments today. I think these will be very useful as they try to implement the intent of this law.

MS. WITTENBERG: One last thing, Maria Beitia and Brenda Ortiz, if you could actually please see me for a second? Thank you.

(Whereupon, the above-entitled matter concluded at 4:26 p.m.)