CENTERS FOR MEDICARE & MEDICAID SERVICES

Moderator: Dan Farmer
July 31, 2012
1:00 p.m. ET

Operator: Good afternoon, ladies and gentlemen. My name is Ryan and I will be your conference operator today. At this time, I would like to welcome everyone to Improving Care for Medicare Beneficiary with End-Stage Renal Disease.

All lines have been placed on mute in order to prevent any background noise. After the speakers' remarks, there will be a question and answer session. If you would like to ask a question at this time, simply press star and the number one on your telephone keypad. And if you would like to withdraw your question from the queue, please press the pound key.

I would now like to turn the call over to Daniel Farmer and David Hurwitz from CMS Innovation Center.

Daniel Farmer: Thank you, Ryan. My name is Dan Farmer. I work in the stakeholder engagement group of the Innovation Center. I'm joined today by David Hurwitz who's the Acting Division Director for Delivery Systems Demonstrations here at the Innovation Center.

Today, CMS is hosting an open-door forum to solicit individual input on ways the Innovation Center can develop and evaluate new models of payment and service delivery to reduce program expenditures while improving the quality of care for Medicare beneficiaries living with end-stage renal disease or ESRD.

Information and perspectives provided by patients, providers, caregivers, suppliers, payers and researchers can provide vital insight to inform the design of innovative model to reduce program expenditures while improving the quality of care for these beneficiaries.

In this open-door forum, we hope to hear from all interested stakeholders. Now, we would like to open up the phone lines to you and any callers who wish to share their perspectives with CMS.

So, with that, Ryan, why don’t we go ahead and just open up the phone lines?

Operator: Certainly. Again, ladies and gentlemen, if you’d like to ask a question, please press star one.

Your first question comes from the line of Diane Wish. Your line is open.

Diane Wish: Yes. I’d like to thank you for this opportunity. And as small providers with, say, that that’s with fewer than 15,000 patients which includes almost every dialysis provider with the exception of two, we would like to understand how we can participate in the demonstration. For instance, will there be a minimum enrolment and can individual small providers come together under a common infrastructure and apply without being a legal entity?

We do – definitely feel that providers of all sites should be included in the pilot and they should be allowed to work collaboratively and to share resources and overhead were not being required to be a legal entity.

We also like to see CKD stage four and five for patients not yet on dialysis and transplantation included in the demonstration. And it’s our opinion that we should consider integrated patient care throughout the whole renal disease continuum if we’re going to achieve the three aims.

And with CKD patients there are significant opportunities to improve quality of care and to reduce the cost of care by having patients begin dialysis with the permanent vascular access since, currently, about 70 percent of all new patients begin with the catheter. And including CKD patients, we’ll also increase the number of patients that choose a home modality and transplant either preemptively or by early inclusion on the transplant waiting list. Thank you.

Daniel Farmer: Diane, thanks very much for that feedback.

Diane Wish: You're welcome.

Daniel Farmer: Ryan, I think we're ready for the next person.

Operator: Your next question or comment comes from William Peckham.

William Peckham: Hi. My name's Bill Peckham and I've used dialysis since 1990 and currently dialyzed at home five or six days a week, (also work due to) carpenter (inaudible) and at work now, so sorry for the sudden noises.

But my concern about these ideas to combine our Part A and Part B cost is that patients aren't averages. And I'm concerned about how the benchmarks are going to be set for these programs. And if they're just set as, you know, global averages or community averages I think you can create some incentives that we're not trying to create.

And I think of myself as somebody who hasn't been hospitalized for dialysis-related reason in 22 years. And so I think I would be, you know, a great person to having your pool but I'm not sure I'm the person that needs to be in the pool.

And so I think there has to be some way to look at patients based on, you know, a more discrete group that matches their cost more closely so that we don't have a situation where the incentive is to get people who are doing well and health into these programs while trying to avoid the people that has a lot of hospitalizations and cost.

And then the further concern about these benchmarks is that you could have providers who are currently doing a good job now, externalizing a lot of benefits to the Part A program by doing a great job providing dialysis and getting people transplanted, keeping people out of hospitals, you know, getting (physical) rates up. And if the benchmark is based on their past performance, then we're locking in those gains that they were doing sort of for free and making it harder to reward them for the job they're continuing to do.

So I think there should be concern about how the benchmark is calculated so that it isn't, you know, rewarding people who, in the past, did a poor job so that their benchmark is a higher dollar amount and making it easier to succeed under the scheme. And I think the experience with Epogen, where the benchmark is set at a higher use level, and so that company's at – were already below – low Epo users. I didn't see the benefit as much as companies that previously were high Epo users. And I'm worried about the same thing happening in combining Part A and Part B.

And just the final point is I would have to say that I think the biggest gains available in improving the experience of dialysis and decreasing the disease burden and decreasing the treatment burden is to engage patients more in their care. So, in general, if – particularly talking about patients who start and finish the year on dialysis, not people who are in transition but people who are using maintenance dialysis throughout the year – I think, for them, the best way to lower their experience – the treatment burden would be to engage them in their care and promote the sort of self-management that's necessary (inaudible). Thank you.

Daniel Farmer: Bill, are you still there?

William Peckham: Yes.

Daniel Farmer: Hey, Bill. I just want to ask you for one quick point of clarification. On that last point you talked about engaging patients in their care. Can you talk a little bit about what you mean?

I know you mentioned self-management. But when you hear – when you talk about engaging patients from their care, what are you sort of envisioning there?

William Peckham: Well, I think there is a big continuum and perhaps I meant one into the continuum. Right. I am responsible entirely for my treatment and manage them by myself and have for many years.

And all the way to the sort of person who, you know, isn't informed about the details of managing CKD and this shows at the center and sticks out their arm, as we say. And what I think needs to happen is to move people away from that into more engagement with their treatments in the center, but also, following, you know, best practices outside the center because 90 percent of the time you're not in a center – you're not under the direction of medical staff.

And I really think we've gone as far as we can go with the leverage that, you know, dialysis units have to improve outcomes. And the people that are most successful that I've met over the years are the ones most engaged with their treatment.

And the details of that would be putting in your own needles, determining your own dry weight, you know, keeping track of your (fistula), washing your hands before dialysis. I mean, some people just don't wash their own hands before dialysis. I think we would see a good improvement in things like infection rate.

And then outside of the dialysis center it would mean, you know, being more aware – the thing that we try to teach people or try to – I know the providers work hard to communicate, you know, the foods that should be eaten in moderation – the techniques people can use to diminish their thirst so they don't come in fluid overloaded.

But, you know, just providing pamphlets and information, I don't think that's done enough. And, frankly, when we talk about, you know, incentives for the providers that would – you know, several thousand dollars we hope would do things that would see an improvement in care, but I know from the patient community I interact with that several hundred dollars would be very motivating to patients and I can't tell you off the top of my head how we could create direct incentives to patients to promote outcomes that we think are important, certainly, fluid control and things like that.

But by putting some direct incentives in there, maybe we could get over that barrier that seems to exist that prevents patients from truly engaging in the sort of habits that can lead to, you know, success. I know that dialysis can be used successfully. And I know that there is people in centers – I know that there is people just like me that don't have the opportunities I had and are suffering as a result and are not doing as well as they could do and it creates cost to the system but it creates human misery, again.

So I think the way out of that is to find ways to get them engaged. And if it requires direct incentives to patients, then I think that's the root we should investigate.

Daniel Farmer: Well, Bill, thank you very much for your comments. Ryan …

William Peckham: Thank you.

Daniel Farmer: … I think we're ready for the next caller.

Operator: Your next question or comment comes from the line of Klemens Meyer. Your line is open.

Klemens Meyer: This is Klemens Meyer from DCI. We think it's important that if there is a demonstration project that it should include transplantation that dialysis providers should be incentivized to promote transplantation and that, above all, there should not be any potential disincentives to kidney transplantation. Thanks very much.

Daniel Farmer: Well, thank you very much, Klemens. We're ready for the next one.

Operator: Your next question or comment comes from (Heather Dollar). Your line is open.

(Heather Dollar): Hi. Good afternoon. I had two really brief questions I'm hoping you might be able to answer at this time. The first is, have you thought about a minimum enrolment number?

Daniel Farmer: So thank you very much for your question. Today, we're really just looking to get public feedback and public input. So we're not going to be responding to any individual questions. But if you have any information or any thoughts on things we should be thinking about, we'd really appreciate hearing that.

(Heather Dollar): Well, based on that comment, then, I would. And that is just when you are thinking about a minimum enrolment number I would just ask that you think about the smaller providers and how best the smaller providers might be able to participate in the program given our patient numbers. Thank you.

Daniel Farmer: Thank you very much for that comment, Heather.

Operator: Your next question or comment comes from Glenda Payne. Your line is open.

Glenda Payne: Thank you very much and I'm speaking for the American Nephrology Nurses' Association this morning and wanted you to know that we do support the development of a special project to focus on improving transitions in care for individuals who do require dialysis treatment.

We really hope that this project would help to reduce hospitalizations and re-hospitalizations. And we think that this population presents really a captive audience, if you will, in many cases to allow improvements to their care.

I certainly support Bill's comments about engaging patients and how important that is to actually make a difference because, in so many cases, as Bill said, they're only in the dialysis unit or on treatment for a very limited part of their life and most of their life they are really responsible for their own care.

Nurses, however, are the health care professionals that are most frequently interacting with this population and, for example, have the opportunity to assess patient who've chosen in-center dialysis as their modality of treatment at least three times a week and can assess home patients at least monthly.

The nurses work with the interdisciplinary team, including the patient, to better manage fluid volume, as Bill mentioned, that's a really risk for complication and is really most of the cause for the heart failure that takes most of our patient's life. Nurses monitor for changes in medications and treatment as the result of hospital stay and they can alert the care team to those changes and educate patients and family in actions they can take to reduce the risk of hospitalization.

With the support of this initiative, I would hope that nurses can institute disease management processes that are known to decrease hospitalization. One request or ask that we have of CMS and CMMI is that any project that seeks to reduce re-hospitalizations, engage the nurses that deliver retained dialysis care and that you ensure proportional representation of registered nurses, including advanced practice registered nurses, in any and all technical expert panels and workgroups formed as part of these initiatives to develop measures or design a project impacting the care delivery to individual-required, retained dialysis treatment.

Finally, we'd also suggest that CMS and CMMI reconsider the use of Telehealth to provide oversight of patients in remote locations, both in-center patients and home patients. With the improvements in technology, we believe Telehealth can be an effective way to facilitate more frequent interaction between the practitioner and the patient. We really appreciate the opportunity for the input into this project and hope you'll consider our suggestions. Thank you.

Daniel Farmer: Thank you very much for that – for that feedback.

Operator: Your next question or comment comes from the line of Tom Hostetter.

Tom Hostetter: Hi. I'm Tom Hostetter. I'm with the American Society of Nephrology and, like everybody else, we're grateful for having this session.

I have three brief points. The first echoes something that a couple other callers have suggested and that's that the late-stage chronic kidney disease be incorporated not just hemodialysis or peritoneal dialysis patients.

We've been led to believe by some people that that – that such patients were unlikely to be in any demonstration project. But, like other callers, we think that would be important for a number of reasons. And also that transplantation be incentivized because if this includes dialysis providers exclusively, that is unlikely to be an area that they have great experience in promoting transplantation. So if you could design a demonstration that would promote transplantation we think, for lots of reasons, that would be good.

My other two points are that we think it's really important that there be some pre-specified evaluative techniques. And from our reading of other earlier demonstration projects, there seems to be a fair amount of dispute about whether the demonstration project worked or didn't work.

And so I realize you're taking suggestions, perhaps, not giving your plans exactly. But we think that's critical and I'm sure many groups, and including the American Society and Nephrology, would be very glad to help you in designing some pre-specified evaluation so that at the end of any demonstration we could have a relatively unambiguous decision about whether it worked or it didn't work.

And the last is the question which you may not be able to answer but since we've been hearing about this for quite a long while maybe you're getting closer. Could you give us some idea of when you might issue an RFP for any demonstration project? Those are – those are my comments and, again, thanks for taking our calls.

Daniel Farmer: Well, thank you very, very much for your comments and thank you also for your question. On today's call we're actually just looking to get input from people. We're not going to be sharing any information or able to respond to that question. But we do thank you, again, for your comments.

Operator: Your next question or comment comes from the line of Sue Rottura.

Sue Rottura: Good afternoon. Thank you, again, for the opportunity to allow us to comment. I am representing the National Renal Administrators Association this afternoon and the NRAA is a voluntary organization representing dialysis providers throughout the United States. Our membership is primarily community-based, small- and medium-sized dialysis organizations, both for profit and non-profit providers serving patients in urban, rural and suburban areas in both free-standing and hospital-based facilities.

We believe our member companies are in a position to coordinate and integrate patient care into their operations to improve the quality of care, patient outcomes and certainly achieve savings for the Medicare program.

NRAA would like to urge you to design a demonstration project that allows for maximum flexibility for independent participation by as many dialysis organizations as possible. We recommend allowing multiple dialysis facilities to form virtual panels of patients, provided that participating facilities would be accountable for all of the patients in the panel and not just their own patients. This concept has been used with private payers in other settings that would not require changes in ownership of the participating dialysis organization.

NRAA also believes any demonstration project should include multiple dialysis providers in each market to effectively evaluate the different approaches to implementing care, deliver changes and modifying current utilization patterns in integrated care models. Most importantly, inclusivity of all provider types in each market will preserve the patient's choice of health care option to produce the most appropriate care for their needs. Thanks again for allowing us to make this comment.

Daniel Farmer: Thank you for offering the comments.

Operator: Your next question or comment comes from the line of (Karen Metzger). Your line is open.

(Karen Metzger): Good afternoon. Thank you for taking my comment. This is (Karen Metzger) and I wanted to echo some of the things that Mr. Peckham talked about with some specificity related to home dialysis users.

According to Dr. (Blegg), less than 1 percent of all patients take advantage of that right now and experienced nephrologists believe that at least 20 percent of all U.S. patients could do this. Much higher percentage of patients get home dialysis in other countries.

It has been shown by research to increase the quality of care, increase the family's participation and family managed care. And I would like to give my name and e-mail or a phone number to either Dan or David or someone to talk to you about the MEDCottage which is a temporary modular health care unit designed to be placed on a caregiver's property.

This would take away the barrier when families want to provide and patients want to have home dialysis but their housing does not make it possible. It's a very high tech cottage that participates in monitoring of the patient and can forward information to nurses and physicians who are working with that patient.

Has a tremendous amount of benefits for the patients in the categories health, wellness, safety and security. And I would ask you to look at that as one way to increase this type of dialysis as a way to increase the quality of care and decrease the cost.

And, lastly, I want to like to say it would be synergistic with the CMS Independence at Home demonstrations where they could be – for it could be taken up as an option. Thank you for this opportunity.

Daniel Farmer: Thank you, Karen. Before you read your phone number and e-mail address for the world to hear, I do want to let people know we are going to be sharing contact information at the end of this call if people have additional comments that they'd like to submit.

(Karen Metzger): I'm happy to give it to you now. I don't – I'm not worried about other people contacting me. I'd be happy to talk to anybody about the MEDCottage (because I) think it offers opportunity for this patient population.

Daniel Farmer: Why don't I just read the follow-up contact information now and you can feel free to send an e-mail there. People who are going to have additional comments should send them to innovation – that's innovation, singular – at cms.hhs.gov. So, once again, that's innovation@cms.hhs.gov and we will be reading that back later in the call as well.

(Karen Metzger): Thank you. That's why I didn't do it until you give me permission, so I'll be happy to send this (inaudible).

Daniel Farmer: Thanks very much.

(Karen Metzger): (Of course).

Operator: Your next question or comment comes from the line of Denise Eilers. Your line is open.

Denise Eilers): Good morning or good afternoon, excuse me. Thank you for allowing me to have some input. I have a few comments.

My late husband was on home hemodialysis for 25 years, worked full time and led a perfectly normal life. I decry what seems to be a decrease in the focus on quality of life issues and renal rehabilitation.

One of the issues that I'd like to mention is a fourth treatment without medical justification. There have been studies recently that show that avoiding what we call the "killer weekend" – that two-day gap means fewer complications and less hospitalizations and re-hospitalizations. The increased cost would be offset by the savings there although, again, we're talking Part A and B.

I also would encourage you that whatever is done with demonstration projects, with advisory committees, anything; include patients and care partners – by the way, I was not a caregiver; I was a care partner – with everything that implies.

Their presence on all committees would ensure that there was true representation no matter – I was just talking to a nephrologist yesterday who said no matter how hard a professional tries, they are not the patient. And they don't know what it's like to live it day and day out. So you need to hear from them constantly.

On the – as an adjunct to that is to encourage any peer-to-peer mentoring programs. I think that's vitally important. Also to encourage anything that encourages maintaining employment or normal lifestyle. To that end, I think dialysis centers open after 5 p.m. need to be encouraged, if not, mandated I guess.

Also to the patient-staff ratio often with social workers especially is very – it's very high number of patients per social worker. And so rehab is not being addressed maybe quite as much as it should be.

And also, my last point, is that I think that any increase incentives fund-wise needs to be tied to patient quality of life and not just simply biochemical markers. Thanks so much.

Daniel Farmer: Thank you very much, Denise, for those comments. Ryan?

Operator: Your next question or comment comes from the line of Robert Ziebol. Your line is open.

Robert Ziebol: Thank you for having this forum. I really appreciate it. I represent (inaudible) Vascular Medical Device Company. And we're developing a device for the prevention of catheter-related bloodstream infections.

And, you know, basically, by preventing the bloodstream infections you can improve health, improve health care and decrease cost, which I know the Innovation Center is very interested in. And, you know – and we're developing a device to do just that.

You know, the results of this we expect to, you know, significantly decrease infections, decrease hospitalization, decrease mortality and basically give the patient a longer healthier life. At the same time, based on our modeling, we expect this to save Medicare and we estimate up to $1 billion per year, so very significant savings.

However, there is a problem with this that – and really leads to an opportunity for the Innovation Center. And the problem is is that the device cost the providers money to be able to use this. And with bundling, the providers today would get no additional payment. So there's a financial disincentive for them to use the product. And, well, at the same time, CMS would be saving money.

So my comment is is that there's a very large opportunity if we can have a payment model that allows for innovation of new products that can decrease cost overall and – but, you know, somehow make it so that the providers are not unfairly having to pay additional cost out of their own pocket. Thank you.

Operator: Your next question or comment comes from the line of Lauren Stone. Your line is open.

Lauren Stone: Yes. This is Lauren Stone and I'm representing Dialysis Clinic Inc. And I just wanted to make a comment that we agree that the demonstration should be based on a shared savings model. If the demo were to be based on a capitated payment system, we're concerned that a number of small dialysis providers would not be able to participate.

And, in addition, we believe that the demonstration should allow for an advance payment option, that this would encourage small providers and encourage broader participation.

Daniel Farmer: Thank you very much, Lauren.

Lauren Stone: Thank you.

Operator: Again, ladies and gentlemen, if you would like to ask a question please press star and the number one on your telephone keypad.

Your next question comes from the line of Allen Nissenson. Your line is open.

Allen Nissenson: Thank you very much. I'm Allen Nissenson, the chief medical officer for DaVita. Just four quick points.

First, just agreeing with Bill's initial comments about the critical importance of patient involvement in – it's not just in whatever demonstration projects the CMMI develops in this area but in overall care, whether it's in care coordination models or other models that the empowerment and participation of patients is critically important to making sure that they are fully-engaged in the process and can help drive the best clinical outcomes.

Secondly, in terms of quality metrics, I think it's very important, as this project develops, to pick those metrics that not only are the most impactful in driving longer survival, fewer hospitalizations, a better patient experience and better patient quality of life that relate to kidney disease, but also the public sector metrics for other diseases. And so as we know much of the – many of the outcomes result from co-morbidities and the management of those co-morbidities.

So we need to make sure that we have a range of quality metrics based on evidence that include those specifically targeted at the kidney disease, but also at other co-morbid conditions but to do so thoughtfully so that those outcomes that may apply to non-kidney patients are not used for kidney patients if they’re not appropriate.

Third, just a response to something Tom Hostetter said. I do want to point out that dialysis facilities, whether they’re part of a large company or single independent facilities, focus considerable time and effort on making sure that patients are informed about kidney transplantation and that patients are referred in the whole process as followed. So I didn’t want you to take away the impression, and I’m sure this isn’t what Tom meant, but just in case, that this is not something that’s currently being done by dialysis facilities.

And then, finally, I think to the ASN point about evaluation of whether a pilot project worked or didn’t work, I want to just add another comment which is I think it’d be very important prospectively as this project is constructed to articulate what is going to happen if the project is deemed successful by whatever metrics are used to make that decision so that we don’t have a project that has a positive conclusion in terms of patient outcomes but then nothing is going to change in terms of the larger care delivery system as a result.

So I’ll stop there. Thanks a lot for the opportunity. I appreciate it.

Daniel Farmer: Thank you very much, Allen.

Operator: Your next question or comment comes from the line of (Helen Miaw). Your line is open.

(Helen Miaw): Hi, there. I’m a social worker and I’ve worked with dialysis patients for about 20 years or so. So I’m just commenting kind of like as an advocate for the patient and I really appreciate the patient actually getting in the line and knowing that this is occurring and stating his opinion.

I think what needs to be understood is that pre-dialysis education helps with adjustment issues and we need to really focus on something like that in order to prevent loss of job, loss of insurance. And that’s really not been a focus. It’s just been as soon as somebody gets on dialysis, that’s when Medicare steps in. So stage four would be a good place to start, if not, before.

Also, the lady was talking about employment. I think employment is very important in order to continue some of our patients in the workforce and utilizing the Bureau or the Department of Vocational Rehabilitation would be a great way to allow the state or federal government to step in and help with that situation by standardizing some of the service delivery processes from state to state.

I’ve worked in four different states as a dialysis social worker and the Vocational Rehabilitation system is different in every state. Here in Ohio it, especially the Montgomery County area, it’s not good at all.

And also the self-care, I heard a lot about that; you’ve heard a lot about that. And I believe that is the way to go, whether it’s peritoneal dialysis, home hemodialysis, it allows people to be more responsible for their care. It allows more support in the home, it takes the burden off of the caregivers in the institution – in the medical institution.

And the question is, why not PD? Why hasn’t that grown? Why are we only at 4 percent in America? Why not home hemodialysis? These questions really need to be asked and to justify why not.

Also with Part B being extended, of course, as long as you can – as long as the patient needs it after – post transplant in order to continue to pay for anti-rejection medication. We have plenty of patients who come back after losing their kidney because they didn’t have maybe $100 or $200 or even $1,000 to pay for medication when that surgery for transplant was like $75,000. And it’s ridiculous that we don’t, you know, have that available for patients. So that’s it. Thank you.

Daniel Farmer: Thank you very much for your comments.

Operator; Your next question comes from the line of Lindsay Punzenberger.

Lindsay Punzenberger: Hi. Good afternoon. My name is Lindsay Punzenberger and I am participating on behalf of the Alliance on Home Dialysis – a new multi-stakeholder coalition that is dedicated to promoting efforts and policies that will facilitate treatment choice (in balance) of care and address barriers that limit access for patients and their families to the many benefits of home dialysis therapy.

We really appreciate your holding today's call. And while I don't have any specific recommendations today, the alliance looks forward to working with you on these issues, specifically related to improving the quality of care for home dialysis patients. Thank you.

Daniel Farmer: Thank you very much.

Operator: Your next question or comment comes from the lines of (Heather Dollar). Your line is open.

(Heather Dollar): Hi. Just briefly I wanted to make sure that any demo doesn't slow improvement and care for patients who are not included in the demo. And any shared savings model shouldn't penalize providers who have already provided better care and lower cost.

So this is really just to comment to (us) when you consider patients in the demo to also think about those outside of the demo and the care – the great care that they may (or maybe) receiving by some (writers). Thanks.

Daniel Farmer: Thank you very much.

Operator: Your next question or comment comes from the line of Richard Berkowitz. Your line is open.

Richard Berkowitz: Hi. This is Rich Berkowitz from Home Dialyzers United. I'm going to proudly repeat some things that other people have mentioned. But considering the original intent of the Medicare entitlement, I think that we're failing patients regarding restoring their lives and putting them back to work and rehabilitation.

I myself am a dialysis patient for close to 10 years. I believe that things like QIP should not be about clinical measures but things that are more meaningful to patients. Patients don't want adequate dialysis but they want good to optimal dialysis.

I think we should get rid of things like Kt/V which many now dispute is not really appropriate anyways and begin to start thinking outside of the box. Let's measure employment. Let's measure home dialysis. Let's measure dialysis center that's being opened after 5 p.m. with new shifts so people can continue to go to work once they start dialysis.

By having more people employed, we're going to be saving money in several different areas including lower disability pay, increasing taxes and increasing income for people, giving them more of a purpose to live which will add years on to their lives.

We need to start getting more serious about more frequent dialysis including every-other-day dialysis for those who are in center. It's interesting that 90 percent of nephrologists in several studies have said that they would do home dialysis if they needed to do dialysis. Yet 91 percent of their patients are prescribed in-center dialysis.

We have to figure out why there is this disconnect. A lot of people think that (fellows) are not being educated properly in schools. A lot of people are saying that nephrologists don't know enough about home dialysis. But it's interesting that they know enough about home dialysis to say that they would do it if necessary.

Believe it or not, but dialysis treats more than just the kidney. It should treat the patient holistically. We need to start looking at the psychosocial issues as well.

And I think we can have demonstration projects and all of the above to look at how each one of those may affect dialysis patients. And maybe we need to look at a new model of looking at how we should measure adequacy and we should look at, you know, just a whole new approach that actually, with the originally approach that was supposedly instituted in 1972. It's been 40 years since the Medicare benefits started and it seems like we've been going backwards.

So I think that, you know, in a sense, to look forward, maybe we should be looking backwards. That's when home dialysis was running at 40 percent as opposed to the 9 percent today. Thank you very much.

Daniel Farmer: Thank you very much for your comments.

Operator: Your next question or comment comes from the line of Robert Blaser. Your line is open.

Robert Blaser: Hello. My name is Rob Blaser. I'm with the Renal Physicians Association, representing that organization. And I just want to make a couple of comment.

First, to the extent that this call is evidence that CMS or is proceeding with an integrated care model in ESRD, we are fully supportive of that. We think it's the right thing to do. It's a warrant to occur. It would be an opportunity lost just because you've got very, as Glenda said, a very captive patient population.

You've got to system and providers out there that have all been doing this kind of thing, so they should be able to do it. This familiarity with alternative and innovative payment models and also with clinical data gathering and clinical performance measures and measurements, to the extent that do you want to make this similar to the ACO model that was released earlier.

I know the issue of being able to provide waivers is something that the Innovation Center has to approach deliberately and purposely. I would say to the – to the – that you can allow for the use of things like allow whoever the entity is to provide transportation for patients and nutritional supplements and that sort of thing. We would urge you to find ways to do so because we think those are key to the success of any kind of – any kind of program of this nature.

And then also, in terms of the things we think that might – that might result from this – we believe that there'd be improved medication compliance, better vascular access care, more home dialysis modality use. I know a lot of folks have brought that up today.

We think that this would encourage that – fewer infections, fewer hospitalizations, increased preemptive transplantation and more consistent management of vaccinations. We think those are among the results that would likely – could come out of implementation of a project like this that we are to go forward, (so) thank you.

Daniel Farmer: Thank you very much for your comments.

Operator: Your next question or comment comes from the line of Dolph Chianchiano. Your line is open.

Dolph Chianchiano: Good afternoon. This is Dolph Chianchiano from the National Kidney Foundation. Thanks again for hosting this forum.

I just wanted to point out that, as Rob has as well, that there is evidence for the value of this kind of integrated care delivery model, specifically in the ESRD disease management demonstration project. And it's interesting to note that in that project 96 percent of the patients who are surveyed and responded to the survey indicated that they would participate again if asked or if allowed to.

Nevertheless, I think it is very important that the demonstration project provide an opportunity for patients to opt out from the integrated care delivery model as they can with the accountable care organization demonstration project.

And also, similar to Rob Blaser's comments – the last speaker's comment – we believe that patients should have benefit from assured savings in the demonstration project and so that they can enjoy benefits not available under

Medicare ESRD fee for service such as oral nutrition supplements, home monitoring equipment, et cetera. Thank you for your attention and we'd be glad to provide any additional information you need.

Daniel Farmer: Thank you very much for your comments.

Operator: Your next question or comment comes from the line of Hrant Jamgochian. Your line is open.

Hrant Jamgochian: Thanks, Dan. This is Hrant from Dialysis Patients Citizens. And, actually, just kind of building on Dolph's comment, you know, one of the things that I think why we're so excited about the potential for a pilot or for a project with CMMI is not only the opportunity to improve patient outcomes.

But the fact is, Dolph was alluding to, the fact that, you know, 80 percent of dialysis patients are on Medicare. And, you know, approximately – and about half of those (are too) eligible and, as a result, things like nutritional supplements if, you know, providers are going to provide them and/or to help, you know, with transportation and/or to, you know, provide other, you know, financial incentives. I mean, that would be considered an inducement.

And by CMMI moving forward with a project like this, the opportunity to waive some of those inducement restrictions to really, you know, help further advance the overall care of this – you know, of patient group I think is one of the things that I think we're, you know, really excited about the potential for.

Obviously, you know, there's a – there's been a lot of really significant data that has been generated and those are just a few examples – areas that have been pretty significant to improve patient outcomes while also reduced overall health care cost. And so, at the same time, I think, you know, as a result, just building on some of the other comments made before, I think we strongly support, you know, as many patients as possible from being able to take – to be able to take advantage and participate in these opportunities.

And that means, you know, small as well as large providers participating, making sure the nephrologists play a critical role in these efforts and then also looking at all the various different models that could potentially benefit patients.

And so, from that point of view, I wanted to thank CMMI again not only for holding this call, for its ongoing dialogue with the organization, with others and within the community and for its interest in this effort. And, you know – you know, I think also for its mission to improve health care outcomes while reducing overall cost.

I can't think of a potentially better area to focus on, not just ESRD patients but also even, you know, pre-ESRD or pre or, you know, CKD patients to potentially focus on the prevention side as well as, you know, transplantation. Thank you.

Daniel Farmer: Thank you very much for your comments.

Operator: Your next question or comment comes from the line of Lori Hartwell. Your line is open.

Lori Hartwell: Hi. My name is Lori Hartwell and I'm the president and founder of Renal Support Network and I've also been a patient since 1968. I wanted to just provide some comments, (learn) support of the integrated care model. But I wanted to share an experience that happened in California this year just so to be aware of it.

They moved the Medicaid patients into managed care and in areas where there were fewer managed care providers, it was very successful. But in the Los Angeles area, where there are multiple managed care providers, it was an absolute disaster.

And to give you an example, a patient would be listed at UCLA for a transplant and then that managed care system didn't have a contract with UCLA that they were put into. And then they would have to go to USC and have the process start all over again.

Another example is a patient started on a catheter and changed managed care system and this allowed them not to be able to have access to a vascular surgeon and the dialysis catheters were left in patients for a very long time.

One of the things that ended happening is the state of California ended up exempting dialysis patients from moving into managed care because it was so disastrous. And I think the key to this is is that, where there were fewer managed care providers, it seemed to be much more effective than a large area where you couldn't manage the care. It was just – it was a very horrific situation for patients at the beginning of this year in California. So I just wanted to make you aware of that situation.

And then, secondly, you know, I've been hearing all the comments about home dialysis and I'm very much in support of that. I mean, I've been on all home treatments. I've been on PD, home hemo.

And I think, you know, one way that would really help is if there was a way to help support care providers in either paying them or – I mean, back in – many years ago, this was a way to improve numbers. And maybe it would help people get home and maybe they could see they could do their care of themselves. But it is a frightening process for many people. So I think that that may be a way to improve home dialysis if you could – if dialysis providers could help pay – if there was some kinds of funds available to help with that.

And then I do agree in a shared savings. I think it's really exciting to have new ways to provide nutritional services or transportation because I know for a fact that transportation is a huge issue for patients. And I've talked to some patients and they, you know, they want to – you know, they want to have an extra treatment transportation, again, is a barrier.

So I think all of those things would help improve the care. So those are my comments.

Daniel Farmer: Thank you, Lori.

Operator: Your next question or comment comes from the line of (Steve Johnson). Your line is open.

Steve Johnson: Good afternoon and thank you for this opportunity. I had a company called CreatiVasc Medical. And it's pretty well understood that CMS and the Fistula First Program are highly encouraging nephrologists and vascular surgeons to attain a 65 percent native fistula placement rate as the initial vascular access method versus AV grafts. Further, Medicaid is threatening to cut off funding for dialysis centers that do not meet this 65-percent level.

I think there is a growing concern that, to attain this 65 percent placement rate, patients whose vein structure could never in the past be considered capable of supporting a native fistula are being given one. And we are increasingly hearing from dialysis centers that many fistulas in these types of patients pose a significant challenge to locate and cannulate.

In addition, these patients are suffering from the fistula not successfully maturing and creating anxiety among both dialysis technicians attempting to cannulate the fistula and the patient who must face missed sticks in the process.

It's recommended perhaps the slogan should be "Catheter Last", and not "Fistula First". Many of these 65 percent fistula patients are being seriously considered for an AV graft instead.

In addition, I would agree with the earlier medical device company caller who expressed concern that the bundling process could be prohibiting new innovation of securing reimbursement. We have such a device called the "fistula finder" which cost a dollar. It's a plastic device that helps locate and cannulate the fistula.

The CMS system said that dialysis centers should pick up the cost for it and the dialysis centers say that this would cut further into their very slim profit margin. So, therefore, it's basically sitting on the shelf.

Clinical trial evidence indicates an 83 percent reduction in interventional procedures to fistulas if the device is used. So it could significantly reduce patient treatment cost and the burden to CMS. Thank you for this opportunity and this consideration.

Daniel Farmer: Thank you very much for your call.

Operator: Your next question or comment comes from the line of Katie Cardone. Your line is open.

Katie Cardone: Hi. This is Katie Cardone from Albany College of Pharmacy and Health Sciences and I am a pharmacist who works with dialysis patients in upstate New York. And I'd like to echo some earlier comments that were made regarding patient engagement or we need to increase patient engagement in their care, not only with diet but with medications as well.

Patients on dialysis are on average of 10 medications per day. And we all know that these can lead to confusion with patients or poor adherence and problems that the medications can lead to – expensive hospitalizations.

We believe that patients on dialysis should be able to see a pharmacist, you know, at dialysis centers. Right now, there's really no mechanism for a pharmacist to be reimbursed when they work in a dialysis facility. Many of us who do work in dialysis facilities do so from academic institutions where we are not paid for our services.

You know, right now, patients can sit down with pharmacists and discuss their medications, update their medication list through Medicare Part D benefits. So if they have complicated medication regimens that are costly, they can be qualified for a service through Medicare Part D. Unfortunately, not all patients have Medicare Part D or even if they do have Medicare Part D and do qualify for a medication therapy management, they might not receive the services or might not receive services from a qualified pharmacist who knows about dialysis.

So I really think that, you know, an optimal care model that incorporates a pharmacist. Right now, patients who are on dialysis receive medications in pharmacies and might have limited interaction with their pharmacists. The pharmacist often knows they're a dialysis patient or a CKD patient by their medication, so if a person has a phosphate binder on their medication list.

However, when the bundle starts in 2014, those phosphate binders will no longer be on the medication regimen and pharmacists really will have very limited ways to know that a person is on dialysis. So if a medication were prescribed by a non-nephrologist, that could be harmful. It would not be caught by the pharmacist and maybe not by, you know, anyone if, you know, it's an urgent-care mediation or something where the medication was dosed inappropriately. Thank you.

Daniel Farmer: Thanks very much for your comments.

Operator: Your next question or comment comes from the line of Kathe LeBeau.

Kathe LeBeau: Yes. Hi. This is Kathe LeBeau. I am a five-year home hemodialysis patient and a waiting transplant candidate and I work with Northeast Kidney in addition to another – a number of other (inaudible). I really do appreciate (this time). I think it's very valuable to bring a patient voice into this discussion.

I'd like to echo some things that had been already said and to take them a little bit further. I think, looking at these projects, it is critically important that patients participate in every level of this both in creating these projects and evaluating them and patient center genuine educated grassroots patients who are (creditable) and not conflicted participate as patient advocates in this process. I think that's paramount.

I think as we look, echoing something that Bill, for example, said. Looking at the continuum of kidney care, I never really understood why the world of dialysis and transplant are so separate. Transitioning through these from CKD to dialysis to transplant is difficult enough on the medical and health side of it, let alone, doing these completely different worlds of care.

These need to be much more closely integrated. I think that's why this potential project is so exciting. And I think what we want to look at is keeping the patients as healthy as possible all the way.

We want people informed and educated about what they can do early on. We want people to understand their modalities and choices and options before they start dialysis. And we want them to be referred early and – (inaudible) early and often for transplant. We really – those are all critically important.

This is – this is the way you create a rising tide of health care of health care for kidney patients, where all boats are listed – everyone gets a better level of care because we're getting broader access to everything and, obviously, as a home patient, I'm a big proponent of increasing access to that.

I think engaging patients – educating patients that they're involvement leads to fuller lives and often better outcomes using a coaching paradigm where patients – successful fellow patients provide – they not only educate and support and encourage, but by the example of their lives, they provide an example of a positive and proactive way to live with chronic illness, sharing things that only patients need to know.

And, lastly, I can't say enough how important I think that we focus on the quality of life and functional wellness. I understand any patient will tell you that this is the important part of their health care, this is the thing that matters to them, and we've had a struggle where it's very easy to find evidence for clinical lab values; it's harder to find a basis for these kinds of measures.

I'm encouraged there is some movement in this area. You know, as recently as April, there was an article in the Wall Street Journal "Looking at the Fact: Establishing the Fact" through Noreen Clark at the University of Michigan Center for Chronic Illness and Rosemarie Kobau at the CDC Quality of Life Center, where they absolutely identified that quality of life is the single motivating factor – the single important factor for people doing better.

So I think it's really critical that that be more and more incorporated as we look at kidney care and I thank you again.

Daniel Farmer: Thank you very much for your comment.

Operator: Your next comment comes from the line of Linda Upchurch. Your line is open.

Linda Upchurch: Right. Thank you so much for the opportunity to make comments. You know, I also (inaudible) much of what has been said. I think we're a small community impacting a large number of patients so (there are) similar things for many of us.

I work for NxStage Medical and NxStage Medical is primarily a medical device company that develops, manufactures and markets innovative systems for the treatment of ESRD, acute kidney failure as well as fluid overload.

As the leader in home hemodialysis and from close partnership with patients, physicians and leaders and our dialysis providers, we're really working much like you are to realize the vision of better, simpler, more accessible care. We'd love to dialogue with you, specifically to discuss potential models and how they might be achieved as well as contribute to (all the) stakeholders who want to lead and facilitate the development of these models.

Specific to home hemodialysis, more frequent therapy has demonstrated the ability to improve survival which is the ultimate goal for all of us and the family members who care for the dialyzers – to provide significant clinical outcome benefits and to potentially increase the likelihood and ability to be listed for transplantation.

As stated by previous (commenters), home patients are much more likely to be employed, they have better self – good quality of life and they are certainly more engaged in their care. So, specifically today, you know, I want to ask for transparency in your process. I appreciate the opportunity to have it on the call, but then I don't want this (inaudible) with the models that are getting developed.

So transparency in how you're developing the models and how to benchmark (the valuable) measures of (inaudible). I suggest that (both of them) patient experience, (include your) patient involvement that Kathy and Bill and Denise and Rich and others have all stated on patient involvement in every level of the development and evaluation of your model.

Make sure that your models promote self-management and home care. Again, we would love to be a part of developing your projects. We would love to be a resource to any of the other callers who have projects in mind.

And we ask that you – let us know if there are other questions. So we'll be giving you some follow-up e-mail and look forward to an ongoing dialogue. Thank you.

Daniel Farmer: Thank you very much for your call.

Operator: Your next comment comes from the line of Cherilyn Cepriano. Your line is open.

Cherilyn Cepriano: Hi. This is Cherilyn Cepriano. I'm the Executive Director of the Kidney Care Council. We represent dialysis providers of all sizes, urban and rural, not and for profit and KCC members treat more than 85 percent of dialysis patients in the United States. Thanks for the opportunity today.

I'm going to comment on a variety of things and echo some of the comments of my colleagues here today. KCC members support, offers integrate care and believe that we actually offer a shovel-ready, if you will, delivery system that is uniquely suited to (these things) like avoid hospitalizations, complications and other cost during (inaudible).

Our membership has a very strong consensus that all providers; large, small, chain, non-chain, urban, rural, not or for profit; should have both the theoretically and actual ability and capacity to participate, if interested, in any demonstration projects to integrate and coordinate care for ESRD beneficiaries.

In our formal comments to the ACO NPRM last year, KCC specifically supported a three-year demonstration with an appropriate scale in terms of enrolment, size and scope that strikes the right balance between facilitating participation by all providers and justifying the upfront cost associated with certification.

And that (inaudible) a demo design construct that would include multiple models most providers could select (submitting) your participation proposal that would enable providers of any size to indentify the model they wish they could demonstrate successful efforts to integrate and coordinate care.

We (have support) here on this call from a variety of scopes, perhaps too many to mention, for shared savings model. There may well be other models such as a (two-quality) extensive model that may also be appropriate.

We'd also believe that some aspects of current demonstrations running in Medicare, such as an advanced payment system offered to some ACOs would help offset the (first) cost for providers and may broaden participation across wider type sizes in geographic location.

I want to echo the comment of Rob Blaser with RPA, Dolph Chianchiano with NNF and Hrant Jamgochian from Dialysis Patients Citizens in saying that we believe an integrated care demo will provide incentives for care innovation (which improves) for the patient outcome and encourage alternative modalities including access to home dialysis and self care as well as transplantation.

Turning for a moment to quality initiative, I echo the comments earlier from Allen Nissenson that there be appropriately-defined quality measures that are targeted for dialysis patients. And we'd specifically say that the more general quality metrics that have been identified for ACOs elsewhere in the Medicare program are likely too broad and not generally applicable to our patient population.

Further, as you know, dialysis providers currently operate with the ESRD Quality Incentive Program or the QIP under a (review) bundle for (stock of) payment system as well as numerous other quality initiatives ranging from Fistula First to ESRD Network Initiative and their parallel collection efforts which include Quality (Clean Day) Reporting as well as CROWNWeb.

As we identify the quality metrics for the integrated care model, it will be imperative to identify and select quality measures that are appropriate for our patients for ESRD and dialysis patients and that are aligned with, and not contrary to, the quality metrics (already) concurrent in the balance of the program.

Finally, Hrant at DPC had mentioned that 80 percent of our dialysis patients are Medicare beneficiaries and that 40 percent of those are dually eligible for Medicare and Medicaid. And I would like to highlight that, as you are running parallel demonstrations underway within the agency and in particular the demo related dual eligibles, we would find it particularly important that anyone participating, say, in the dual project would be able to come and participate in the ESRD project.

As ESRD is frequently the primary driver of care for our beneficiaries, we think it will be an important element to be able to coordinate a care not just for Medicare but for dually-eligible Medicare and Medicaid beneficiaries.

The KCC is in the current process of thinking deeply about these issues. We appreciate the opportunity to comment today. But, more than that, we very much like to work with your going forward, attend to these very important technical issues where we believe our members can provide a lot of experience, expertise and really work to improve patient care as well as assigned programmatic savings. Thank you.

Daniel Farmer: Thank you very much for those comments.

Operator: Your next comment comes from the line of Tom Hostetter. Your line is open.

Tom Hostetter: Hi. I spoke earlier. I would just want to clarify something that Allen Nissenson raised with regard to transplantation.

I didn’t want to imply that the providers are unaware of transplantation. Most providers do a good job of tracking the numbers of patients on the list, encouraging it and educating patients.

But I would see a demonstration project as a chance to up the game – to increase – to increase the integration with the transplant centers and to encourage it even more. We heard some of the problems in Southern

California from Lori Hartwell when integration is done wrongly and dialysis providers and transplant centers are not well-aligned.

So I would encourage – I would see this as a place where you could help the providers to encourage transplantation more and encourage integration with the centers that actually do the transplant. And one part of transplantation which has not been under the purview of providers, and again, I would hope the demonstration project could bring this in, is in preemptive transplantation that these patients who are not yet on dialysis and have a donor and can be worked up and transplanted before they even need dialysis.

In that regard, and my last comment is that I think it would be wrong to imagine that a primary care ACO with a primary care physician, not a nephrologist, was in a position to advice and educate a patient about that choices they were facing end-stage renal disease treatment – the choice being preemptive transplantation.

So I – in clarification, I think this is a time or an opportunity to actually enhance the understanding and provision of transplantation over what we – what we do now. Thank you.

Daniel Farmer: Thank you for those comments.

Operator: Again, ladies and gentlemen, if you'd like to ask a question, please press star and the number one on your telephone keypad. Your next question comes from Harold Manley. Your line is open.

Harold Manley: Hello. Yes. My name is Harold Manley. I'm with Dialysis Clinic Inc. and I'm also a pharmacist. Thank you for this opportunity to comment on this pilot program. I want to echo the concerns or the issues raised by Dr. Cardone from Albany College of Pharmacy.

As a pharmacist, I, too, think that the pilot program should include pharmacists' involvement in the management of these patients because, as stated and as we all know, they're very complex, they take a lot of medications. And medications are used not only to treat the ESRD-related issues but also the many co-morbid conditions and can lead to hospitalizations if mismanaged or lead to re-hospitalizations if mismanaged. So to have a pharmacist as part of the health care team in the care transitions as these patients go and out of the hospital or even go on to dialysis initially I think would be a great intervention.

And also thinking that, as part of the team, having this, I guess, that skill set offered to the team would help manage the patient overall better. And that actually has been demonstrated in the ESRD – to these management demonstration projects as well as some – a randomized controlled trial and some observational trials, including pharmacists and this patient population of care.

So I'll keep my comments brief. But, again, just to encourage that pharmacists be part of the team in managing these patients. Thank you.

Daniel Farmer: Thank you for those comments.

Operator: Your next question or comment comes from the line of (Diane Wish). Your line is open.

Diane Wish: Yes. I just like to reiterate that I definitely believe that this should not be a capitated program since it would eliminate most small providers and that it should include shared savings and allow for the exempt payment option for small providers to encourage broader participation.

Ohio – I'm from Ohio and Ohio I guess has already been approved for the Duals Project. And I agree with the comments by Cherilyn from KCC that I believe that if a patient was approved into a demo that the patient should be allowed to opt out of the Medicaid Dual Project in favor of the integrated care pilot if that was approved by a provider in the area. Thank you.

Daniel Farmer: Thank you for those comments.

Operator: Your next question or comment comes from Lisa Hobson. Your line is open.

Lisa Hobson: Hi. Thank you. This is Lisa Hobson. I'm the quality focus coordinator from DCI.

In our focus on trying to decrease catheter rates and increase fistulas in patients who are candidates, one very large barrier is the fact that hospitals or surgeons will not get reimbursed for access placement before 90 days of dialysis. And, therefore, the patients who crash into the ER automatically get a catheter.

And we often cannot get the (inaudible) the access process even started until after day 91 which then, if the patient is a candidate for a fistula, will still not get their catheter out for at least another 120 days. So during those first months the patient is being robbed of opportunities for improved outcomes because catheters affect almost all measureable outcomes.

And we've also seen that patients who start with the catheter are often more reluctant to go back to the hospital for a surgery or other psychosocial issues that have already been mentioned on the call, like transportation inhibit the process and make it a longer process.

So we know starting dialysis with a catheter increases the risk for infection and hospitalizations and, therefore, cost and could also prevent delay – prevent or delay transplantation. So, therefore, we'd like you to consider payment for permanent vascular access placement from day one in – without considering how long they've been on dialysis. So thank you for taking my comment.

Daniel Farmer: Thank you very much for calling.

Operator: Your next question or comment comes from the line of Joyce Jackson. Your line is open.

Joyce Jackson: Thank you. Yes. I just like to comment on the issue that I think Lori Hartwell brought up that having many providers in some kind of pilot or demo.

I think it's really important that in this demonstration that there be the opportunity for a variety of providers, any region, to participate in a demo so that there's not an exclusive franchise, so to speak, for one participant in a region. But that there be multiple ESRD providers who can independently be part of the demonstration and experiment and innovate to create new knowledge about how to better take care of our patients.

The second point I'd like to make is that the size of the demonstration is going to be critical for smaller providers to participate. Let's say, a provider has maybe 500 Medicare patients, we would hope that, if there are quality incentive payments, that those are not so small – 1 or 2 percent – that would not be adequate to fund the upfront innovation and investment of transition care coordinators, CKD programs, IT systems, et cetera. So those incentives through shared savings or QIP payments afterwards really do need to be proportional to the investment.

And, third, I would hope that the providers could work together, if they do have 200 or 300 or 500 patients, to come together to form a minimum-sized group whether you determine that's 5,000 patients to be in an integrated care demo and not have to form a whole new company or a legal entity, but together to be able to participate.

So those are my points. Thank you very much.

Daniel Farmer: Thank you for those comments.

Operator: Your next question or comment comes from the line of Sarah Fenwick. Your line is open.

Sarah Fenwick: Good afternoon. Thank you for allowing us to have the opportunity to give our comments on the ESRD program. I represent long-term care pharmacies and our patients inside the facilities that our pharmacies serve run into patients who are receiving dialysis.

And I'd like to delve too on the comments that the other individuals that represented pharmacy and say that long-term care pharmacies need to have consideration as to how they coordinate the care of the medications that are used for ESRD patients and where those medications should get dispensed under the prospective payment program where the, you know, the drugs are being covered underneath Part B in the – in the – in the dialysis facility.

The challenge that our long-term care patients have is that they leave the long-term care facility, go to the dialysis facility, receive care and then go back to the long-term facility. And, oftentimes, the pharmacies that are working with those long-term care facilities are responsible for providing those drugs to those patients because they provide it in a manner that the facility needs to properly administer the medication.

And when you consider what is being asked of long-term care pharmacies, underneath the short-cycle (still) requirements that go into place January 1, 2013, I think this is also another element to help reduce waste in the long-term care setting, to ensure that, one, patients are getting the medications that they need and the right dose.

And if the patient is discharged or the patient ceases the medication or the patient passes away, that all of these elements to be taken under consideration for that long-term care facility because it places a burden on, not only the facility to manage meds that might be coming back from a dialysis facility, but how they coordinate that care and where they should get their medication from for that patient and how it affects their pharmacy that they use to get the medications.

This has been a challenge since the ESRD prospective payment program began in January 1 of 2011 with Part D sponsors not knowing whether or not these products should be covered or not. And so I just ask that the long-term care pharmacies being taken into consideration as you develop the guidance going forward for how this program will work and how we coordinate care for these patients. Thank you.

Daniel Farmer: Thank you for that feedback.

Operator: Your next question or comment comes from the line of William Peckham. Your line is open.

William Peckham: Sorry about that. (Inaudible) mute. In listening to this call (inaudible) I appreciate the opportunity to participate.

But I realize that we’re operating a little bit in the dark here because we’re imagining a system that will lower overall cost. But I don’t think any of us compare cost on a patient-by-patient basis. I don’t know what my total cost is, let alone what the total cost per patient is at a unit in my community or in my state.

And I think, you know, if we’re going to try to target something that we should have the data that tells us, you know, where we stand now. And my suspicion is is that, you know, it’s going to be a – some of bell curve that shows the cost and at one end will be people like me who (cashes) almost entirely Part B.

And then others will have, you know, much more significant Part A cost. And I would suspect – you know, I would hypothesize that if you looked at cost year to year to year that, you know, one way we could identify who’s going to be most expensive in 2013, from the point of view of this system, would be to look at who is most expensive in 2012.

And without that information I don’t know how we could really target those people other than just to imagine that people with high hospitalizations would be high cost. But I think there would be a lot of detail that we should (gleam) from the total cost numbers if they could be provided, you know, more discretely, you know, by the community, by the state, by the network, but best by the – by the unit.

And I could imagine that we would look at total cost per unit. So if we were thinking about 2015, we’d look at the total cost for the most recent year for the unit and that would inform the benchmark much more than the total cost for the community. Or it would be the total community cost, not including the total cost for the unit.

You would exclude the unit we’re talking about when determining the benchmarks so that you don’t reward people who have poor performance in the past or disadvantage people who had good performance. But, you know – and thinking about this, I don’t have that information.

I don’t – I know that the averages are – 85,000 I think is the number we hear a lot. But I also know that number includes skilled nursing and it includes things that aren’t relevant to every patient. And so to get better average at cost numbers I think would be really important.

So that you would look at my historic average cost to determine what my benchmark was rather than using a national benchmark or a state-wide one. So it would be really helpful to make that information available and we could start looking for clues on who to identify the target for interventions because I think we would find that, you know, some patients are much, much more expensive than others and they would need maybe more direct targeting, whereas, myself, you know, I think the system is doing a great job for me and maybe I don’t need as much. But I think we could really use more data. Thank you.

Daniel Farmer: Thank you very much.

Operator: Your next question or comment comes from the line of (Steve Johnson). Your line is open.

(Steve Johnson): Yes. Could we have the e-mail address? I attempted to use innovation@cms.hhs.gov and it bounced back.

Daniel Farmer: Yes. Hold on just one moment. I want to verify that. So the e-mail address should be innovate – singular – at cms.hhs.gov. So, again, that’s innovate@cms.hhs.gov and “innovate” should be singular.

(Steve Johnson): Thank you very much.

Operator: Your next question or comment comes from the line of Eduardo Lascon. Your line is open.

Eduardo Lascon: Hello. Thank you for the opportunity to comment. I am from Fresenius’ medical care and part of my work includes evaluating quality metrics.

And for this innovation demo I would like to recommend that there be a chance to individualize management for the outliers because we have a tendency to evaluate quality across the board and the denominator may be appropriate for 90 percent of patients to 95 percent but there would be some patients that the standard that's currently in place may not be appropriate.

And I'd like to refer you to a paper that was written by Dr. Tamura, Dr. Tan and Dr. O'Hare in Kidney International. It's volume 82, 261 – pages 261 to 269 and it's entitled "Optimizing Renal Replacement Therapy in Older Adults: A Framework for Making Individualized Decisions".

And maybe it is within this demo where an opportunity exists to be able to provide creative management for individualizing based on patient preference, prognosis and the competing choices for patients, whether it's on modality, whether it's on vascular access and whether it's on palliative care. Thank you.

Daniel Farmer: Thanks very much for those comments.

Operator: Again, ladies and gentlemen, if you would like to ask a question, please press star one. And we have no further questions – sorry – one more question on the line from Gary Peterson. Your line is open.

Gary Peterson: Hi. Thank you. This is Gary Peterson. I've been involved for – in dialysis for 37 years – the last 13 years as the editor of RenalWEB and I'd just like to make a few broad statements on technology development, what patients want and the goals for the federal ESRD program.

This is the 40th anniversary of the Federal Dialysis Program and I think the people who sponsored that legislation originally would be shocked at how little progress has been made in terms of allowing patients to lead normal lives.

When you compare dialysis with, say, type one diabetes, 40 years ago, those children led very regimented lives. And, today, they lead largely carefree lives.

So when we look at what went wrong, I think we've had the wrong incentives. You know, if we look at our machines, for example, we've been relying on the same old dialysis technology for decades. The largest dialysis machine manufacturer essentially sells the same machine they've been selling for the last 25 years.

Little progress has been made except for the next stage machine and making the machines portable, convenient and easy to use – I'm speaking of hemodialysis machines. And when you look at the people that are focusing on improving dialysis patient care right now, they're mainly focused on improving survival and hospitalization rates and cutting overall cost. And their plans tend to revolve around further medicalizing the patients' lives. So it makes the likelihood of them living a normal life, you know, less likely.

And I think if you look at what's going on in large corporations, we do not see them attempting to increase patient employment and rehabilitation. We have been able jettison these sponsors from the corporations with no objection from Congress or CMS. The majority of the clinics do not shifts that even start after 5 p.m.

So I'm thinking about this. The question I keep asking is, what do patients want? And I think the answer that everyone should keep in mind is that patients want to live as normal lives as possible.

And I think if you look at the federal ESRD program and start asking questions about what is the best goal for, you know, replacement therapy or what would bring the most improvements and innovations to renal replacement therapy? Or what is psychologically best for the patients? It's the same answer. It's that patients want to live as normal lives as possible.

So I think that the tendency right now for physicians, corporations and even CMS, too, have embraced a herd medicine approach instead of focusing on individual patients. So when you think how we can change this around – how do we unleash the genius and the driver of U.S. entrepreneurs and university system, investment firms and patient to improve care, to get better machines.

I think if you provide incentives for normalizing patients' lives, and it's very hard to come up with a marker to indicate that, but probably the best one available is employment to working age patient. If we try to keep working patients who are coming in to the ESRD employed, and provided a financial incentive for that, I think that would drive all kinds of innovations, not only in technology but also in the system of care.

And probably the most powerful incentive is to extend the MSP period for employed patients as long as they stay employed. Now, that may be outside the realm of your powers and capabilities, but you may – you may be able to recommend something like that. So that's about it and thank you for this opportunity.

Daniel Farmer: Thank you for your call.

Operator: We have no further questions in the queue.

Daniel Farmer: All right. Well, I will begin to wrap up here. If people have additional comments that come to mind, please feel free to go ahead and jump back in because we do have some additional time. But in the interim, I want to thank everybody for joining us on today's call. We really appreciate the valuable input we received today.

If you have additional perspectives that you would like to share, you are welcome to e-mail the Innovation Center at innovation – singular – at cms.hhs.gov. So, once again, that's innovation@cms.hhs.gov.

For those who are interested, a recording of this open-door forum will be posted on the Innovation Center website in the coming weeks. And the Innovation Center website is at www.innovations – plural – dot cms.gov. So again, that's innovations.cms.gov.

One final note, today's call is intended for stakeholders only. This was a call that was not intended for press. So any comments made today should be considered off the record.

So thank you again all for joining us today. We hope you have a wonderful afternoon. And please continue to stay engaged with the work of the Innovation Center. Ryan, I think we're finished.

Operator: This concludes today's conference call. You may now disconnect.

END