CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

ADVISORY BOARD MEETING

DEMONSTRATION OF BUNDLED CASE-MIX ADJUSTED PAYMENT SYSTEM FOR END STAGE RENAL DISEASE (ESRD) SERVICES

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The meeting was convened pursuant to notice at 9:00 a.m., ROBERT RUBIN, Co-Chairman, presiding.

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P R O C E E D I N G S

CO-CHAIRMAN RUBIN: I would like to welcome everybody to the second meeting of our Advisory Board on the Demonstration of Bundled Case-Mix Adjusted Payment System for ESRD Services. That's about the biggest mouthful I'm going to be able to spit out today.

For those of you who have the agenda, you'll see that we're going to go from now until roughly about 12:15. There is a lot of expository material. We're then going to have about two and a half hours for discussion of the material that's presented. Then, hopefully, the recommendations will actually be recommendations/instructions for further analysis of a more narrow set of parameters towards a bundle than what was presented in the material that was distributed to the committee.

As we go through this expository material, it would be helpful -- as you can see, it's a pretty jammed agenda -- if we could keep the questions to matters of clarification and/or fact, rather than comments on what the data are telling us. I think that's really what we want to look for in the afternoon.

Having said that, we'd like to approve the minutes that were of the last meeting. I'm sure everybody's had an opportunity to review them. Does anyone have any comments? I think a motion would be in order.

DR. LAZARUS: So moved.

DR. WISH: Seconded.

CO-CHAIRMAN RUBIN: Seconded. All those in favor?

(Chorus of ayes)

CO-CHAIRMAN RUBIN: Opposed? Okay.

Well, with that news, we're 25 minutes ahead of schedule, and let's hope we can stay on that positive note. I'd like to turn over the microphone to Henry Bachofer, who's going to make a presentation on a review of alternative bundles.

MR. BACHOFER: This is actually just sort of an introductory presentation to sort of orient everyone and bring everyone up to the same point in terms of understanding the structure of the options we're going to be looking at today and sort of lay the ground work for some subsequent discussion. We may be able to pick up a little more time because we've also allocated a fairly

hefty chunk for this, which may not take as long.

CO-CHAIRMAN RUBIN: I suspect there will be enough things to fill up the time on this section.

MR. BACHOFER: I suspect that there will be as well, so, again, any clarifying questions are of course welcomed.

Essentially what I'll be doing in the next few minutes is outlining the general framework that we developed following the last meeting for thinking about what the bundles are, various ways of conceptualizing the bundle payment and the elements or the components of that bundle. The goal of this process is of course to continue to support the Advisory Board in your fulfillment of your statutory charge. I'd like to just take a moment and review what that charge was, which is to advise the secretary and the administrator of CMS concerning the establishment and operation of a demonstration of a fully case-mix adjusted payment system that includes, "drugs and biologicals, including erythropoietin, furnished to in-stage renal disease patients, and clinical laboratory tests related to such drugs and biologicals." So in effect we've taken that scope and then sort of broken it down into

components of what might go into that bundle or how you might think about elements of that bundle. There will be a little bit of reputation here from subsequent presentations as well, but we'll skip through the subsequent ones a little bit more quickly.

The starting point for this -- and this actually goes back to some work that Brady did after the last meeting, if I can blame him for it -- is the notion of trying to come up with or conceptualize a continuum along which you might position various bundles. There's sort of two axis in this diagram. The horizontal dimension is essentially going from a fee-for-service payment system for individual services that are provided by the dialysis facility to individual patients, running along the spectrum as you go to the right, to full capitation, which would be all of the services that are provided by all providers, including in-patient hospital services. So in a sense, as you go from left to right, the size of the bundle is getting bigger and bigger and more and more resources are being included in that bundle.

There is, however, also a vertical dimension, and that is sort of the extent of the facility's influence on

the cost or the resources that are then included in bundles as you go along. At the very bottom is the composite rate, where there's a fairly large amount of facility influence on what goes on within that bundle of services in terms of the staff, supplies, and so on and so forth.

As you go higher up towards the top of the diagram, the ability of the facility to directly influence the resources that go into the bundle diminishes. At least that is the sort of the hypothesized direction of that.

As we go up the bundles we've really defined two broad categories, the sort of Bundles 1A through D, which reflect the services that are provided either directly by the dialysis facility or that are provided through the dialysis facility and/or under arrangement of some sort. Those would include Bundle 1A, which would be the composite rate services, plus selected drugs -- in this case the three major drugs, which would be EPO, iron and Vitamin D, plus laboratory tests that are in some sense related to anemia and Vitamin D management.

This classification -- actually, a couple of people have already asked about that -- is we've classified laboratory tests somewhat arbitrarily into some categories,

although we did use some significant clinical input, to try to sort out where the lab tests fit into some broad categories related to these drugs. So Bundle 1A would be iron, EPO and Vitamin D and the lab tests related thereto.

1B took a next category of sort of major drugs that had been identified by the Officer of Inspector General and in other studies that are significant sources of costs, and that would include primarily Levocarnitine, Alteplase, and Vancomycin. Then the lab tests related to that, which we've classified generally as either lab tests related to infection or lab tests related to carnitine.

One comment on that is that we recognize that all of those cases, the lab tests themselves are not exclusively used for those purposes, and so they are used for multiple purposes outside of that narrowly-defined category, but we've got all of the lab tests that fit into that category in here.

The third bundle up at 1C would be the composite rate services and all drugs that are provided within the dialysis facility and billed by that facility -- at least that's what we're trying to get to there, and then all laboratory tests that are either provided by the facility

or that are provided through a laboratory that is affiliated with a facility. There are somewhere around 260 or so of those lab tests in total. We'll go through that in a little bit more detail.

Finally, 1D simply takes everything else that appears on a claim that is submitted by a dialysis facility and adds it into the bundle. I'll comment a little bit on that when we get into that discussion later on.

Effectively what happens as you go from Bundle 1A up to 1D is you're going from a fairly narrowly-defined but significant chunk of resources related to three drugs to all of the services that are provided by the dialysis facility.

The next two bundles, sort of a second category, are beginning to reach outside the dialysis facility itself and to bring in resources that are not so directly controlled by, if you will, or managed by, or influenced by the facility. Those would be the MCP payments to the nephrologist under 2A, and then Bundle 2B would be services that are related to the vascular access. Again, we'll be talking about that in the next presentation, those two bundles.

In effect, what we'll be doing this morning is reversing the sequence that I just went through, and we'll begin by talking through the bundles 2A and 2B, and then working our way down into a longer discussion under 1A.

Paul?

DR. EGGERS: A minor sort of point, but it looks as though maybe it ought to be 2A and 3A, because B is not just an addition on to 2A, it's a different sort of thing.

MR. BACHOFER: There was sort of a artifactual issue. We actually started off with 2 of 3, and then just for purposes of labeling.

DR. EGGERS: I just wanted to make sure that it wasn't MCP plus vascular access.

MR. BACHOFER: No. In this instance we had initially looked at it as doing MCP and then MCP plus vascular access. But in the way that we ended up thinking about it, we approached that as two separate issues. Again, we'll talk about that in the next major section.

So that's essentially the notion here.

DR. OWEN: Dr. Lazarus, can you pressure-test this idea on facility influence on cost? Do you buy that, as for the gradation that's offered there?

DR. LAZARUS: Probably, yes.

MR. BACHOFER: Okay. So that was sort of the structure of options. The second issue that we were trying to deal with was to begin thinking through some of the policy questions or considerations that might guide where you come down along that continuum. A lot of different options had been proposed, notions of the coordination of care, access to care, quality of care issues, and so on. Sort of a late edition to where we ended up on this was to sort of pick some of the thinking that we had done under pay-for-performance and looking at the framework that had been proposed under the Institute of Medicine studies related to the quality chasm, and say that from a policy point of view there are some criteria that we might want to apply or questions that we might want to ask.

Does a particular bundle, for example, under safety increase or decrease the risk of patient injury? A bundle that includes more services, arguably, may reduce risk of injury to patients. Brady likes to talk about the issues that are related to dry blood specimens and so on. The fewer people you have sticking the patient, who or may or may not know what they're doing, the less of a risk

there is to the patient. So arguably as you go towards more inclusive bundles you may be reducing risk for patient safety.

CO-CHAIRMAN AUGUSTINE: Henry?

MR. BACHOFER: Yes?

CO-CHAIRMAN AUGUSTINE: Let me just add real quick. I know I'm not supposed to make comments, but this is really the foundation that we need to evaluate what we're doing against. So we need to keep these IOM names in mind as we go through the day.

MR. BACHOFER: The second dimension would be effectiveness; does moving to a particular bundle create issues or create incentives to reduce excessive treatment; does it create incentives perhaps to move in the direction of under treatment of patients? There are various questions about effectiveness and its relationship to the scope of the services that are included in the bundle as well as some other questions.

Thirdly is patient centeredness. Does a particular bundle enhance or impede the extent to which patient preferences influence choice of treatment, modality and so on, and is that related in any way to the scope of

the services that are included within the bundle.

Timeliness of care; does the bundle encourage prompt response? This may be one dimension, for example, of coordination of care. If there is an incentive in a bundle to not provide services in the facility but rather to refer patients outside of it, it could have the effect of diminishing timeliness of care. On the other hand, putting into the bundle may encourage the facility to do more for the patient while the patient's there, so you could get an improvement in the timeliness.

Efficiency is really looking at the question of what are the facilities both for the delivery of care in an efficient manner, the use of efficient mixes of resources, negotiation of efficient prices and so on and so forth, but also administrative efficiency; is there a reduction in the administrative burden associated with one of these or another.

That could work in a number of different directions, depending on where you are with a bundle. A big bundle might be more efficient in some sense, but it also means that you are requiring the dialysis facility to do more work related to claims or services that may be

coming from outside the facility. So there are issues that have to be weighed there.

Finally, equitable. Might the bundle have an adverse of a favorable effect on the availability of high-quality care to all patients, or are you creating a system in which certain types of patients may be disadvantaged or facilities may be disincented to take care of individual patients.

That's about it for the basic structure that we have and that we'll be looking as we go into some of the data over the next 45 minutes or so that we have from the descriptive side.

CO-CHAIRMAN AUGUSTINE: Henry, if you can, during your discussions, speak up a little more. We're getting some comments from the phone that they can't hear.

MR. BACHOFER: Okay. I will endeavor to do that without getting any feedback loop going here.

CO-CHAIRMAN RUBIN: Is there a phone light near you?

MR. BACHOFER: No, there is not.

CO-CHAIRMAN RUBIN: I think that it's going to be insurmountable problems since this microphone is

permanently ensconced behind the projector which is making noise and the speakers are back there.

MR. BACHOFER: Is there a way that we can --

CO-CHAIRMAN RUBIN: But let's keep rolling while the technical folks try to solve this issue.

MR. BACHOFER: Okay.

As I indicated, we're going to sort of walk our way backwards through this. I handed out a presentation on MCP and vascular access payments. For people who are listening on the phone, unfortunately we can't send this to you from here. This actually goes under Tab E, so it goes in the placeholder in your notebooks.

Our goal in this part of the presentation is really to look at these two more broadly-defined bundles, and to sort of look at some of the issues that arise if we were to try to expand the bundle to include some of these services and what the potential effects are. Most of this discussion I think will end up being about technical issues that arise under these for reasons that will become apparent as we go through the day.

My purposes here are to review the goals of expanding the bundle, to include these components, to

discuss the nature of the data that we have available to us, to look at these options, to review what we know about variations, specifically in MCP payment. We had hoped to be able to do the same for the vascular access issues, but for reasons that I will discuss, that proves to be a much more challenging task than we had anticipated. And then finally, we will review some of the administrative issues on each of the options that I believe are relevant to a decision to try to implement such an expanded bundle.

Just a notice to the reader here -- you'll see this on a couple points today -- I want to be very clear on who's responsible for what opinions, and what data analyses, and so on. Our contractor, KECC, has basically run all of the data for us on this. We have massaged that data to a degree, and any of the comments that I am making here are comments from CMS staff. They are not official CMS policy. They are sort of perspectives of the analyst who is responsible for it; namely myself. With that disclaimer, we can go on.

The bundling continuum provides a starting point for this. Just what we're looking at are just those top two items, the vascular access services and MCP. We'll

start with MCP and work our way up.

Both bundles would include services that are not directly under the influence or control of the facility and both are involving services that are at present, not billed through the facility. Both would then imply a significant change in organizational relationships between the facility and other providers. Bundle 2A would add to the facility payment the MCP payment that is currently going to nephrologists. Adding the MCP payment to the bundle would have an obvious impact on the organizational relationship between the nephrologist and the facility, but it would also, obviously, have an impact on the financial relationship between the two.

The same can be said for vascular access, but sort of multiplied by a degree of complexity here. The additional payments would include payments to hospitals for both inpatient and outpatient surgery and other diagnostic and other ancillary services. They would involve incentives. They would involve physicians who are surgeons. Although it wouldn't involve payment to those surgeons, it would require the facility to establish different kinds of organizational relationships with

surgeons than perhaps they have today and so on. So it would clearly on the financial side require the facility to establish financial relationships with the other providers of the surgical services that are involved and other diagnostic services that go into vascular access procedures.

Concepts or goals. Given the magnitude of the organizational impact of this, it is worth pausing and thinking about the concept or the goals. We are looking at these because at the first meeting of this group there was a significant amount of concern expressed that perhaps this narrow bundle meant that we were being not ambitious enough, meaning that we needed to look beyond sort of this narrow range of services which was related to dialysis, and start looking at other things that are going on in the care of the patient that also affect what can go on within the dialysis facility, and the two most important of those being what it is that physicians are doing and what it is that is going on with vascular access.

So what we were attempting to look at is reaching beyond just dialysis and look more broadly at management of ESRD. The notion is that the broader bundle might provide

you greater possibility for changing incentives, affecting the care provided to patients, concerning some of the determinants of costs, of dialysis itself, use of drugs and so on. The hope would be maybe to move in the direction of a system that creates more comprehensive incentives.

The goals, however, of a broader bundle are pretty much the same and consistent with the goals for the more narrow ones. They are first to encourage the adoption of a broader perspective on the responsibility of the facility, to take a broader approach to managing resource use by the patient; second, to create stronger incentives and means of encouraging care across a range of providers; thirdly, to increase the ability of facilities and affiliated practitioners to find innovative ways of meeting patients' needs. That is to say it should increase flexibility.

The questions that arise that we'll be going over are technical implications of attempting to move in this direction, the potential benefits of expanding the bundle to include those services, and the potential risk of expanding the bundle as well as the administrative implications.

Before we get to actually look at any of the data, we have to go over the caveats that are associated with it, so bear with me for just another moment here. This is specifically on MCP. The first part, the limitations of the MCP data that we have are that they come from 2003. They therefore do not reflect new payment policies. They do not reflect any behavioral response to those payment policies. It means that we are significantly limited in terms of understanding the actual physician inputs, if you will, or resources that are expended on individual patients over the course of the month because of the characteristics of the older MCP payment formats.

Unfortunately, there is no way that we can compensate for that in the data. If we change fee schedules, for example, we can reprice claims. But, unfortunately, the new payment uses new codes. Those new codes don't exist in the old data, and so we can't sort of update the data to reflect the new payment policies, a non-trivial problem.

Thirdly, the scope of services that we are capturing in the MCP is of course just the MCP payments. It doesn't include all payments to the nephrologist and it

certainly does not include all payments to other physicians as well. So it is still fairly narrow in its focus in that it is not broadly affecting physician payment. And finally, because of the limitations of the data, as we'll see in a minute, the data display relatively little variation across pages, a point that we'll come back to.

The problems with the vascular access bundle are a little different. The most important of which is that the scope of the vascular access services is extremely ambiguous. It includes surgical services and related diagnostic services. Those surgical services might be performed on an inpatient basis. They might be performed as part of another inpatient stay for another unrelated condition or reason for admission, although I'm curious about how frequently that would occur.

It might include outpatient hospital surgical facilities. It might include other surgical facilities that are outpatient. It might include services from hospitals for radiology and other diagnostic and ancillary services, as well as other sources for those services. So it's a large number of different kinds of providers. It's very difficult to pin down the specific procedure codes and

other things that are clearly and unambiguously related to vascular access. Also, then, there would be issues related to identifying separately services that are related to maintenance of access as opposed to initial establishment of access. All of those we'll come back to in a second.

The MCP payment is viewed as significant because although it is a relatively small contribution to total cost, it is viewed as potentially creating some leverage for encouraging more efficient and effective management of care, at least by people who would propose including it in a bundle.

To put a little number on that, in general the MCP payments represent about 10 percent of total payments on a monthly basis. It would be the same on a per session basis because of course you'd be dividing by the number of sessions. But it's about 10 percent of the total. We'll see that again in a minute. Nonetheless, although it is a small percentage, there is a thought that perhaps it could create some leverage.

Including MCP payment in the bundle may, however, have some significant analytic implications or we'll have to deal with some analytic hurdles, the first of which

there's relatively little variation in MCP payments across months. It is prorated in a sense based on number of days that the patient is under the care of the facility, and there are geographic area factors that apply to the payment. But beyond those two characteristics there's relatively little that affects the MCP payment at the patient level. Again, we'll see that in a second.

As a result, patient characteristics -- and this is the implication really for case mix -- have relatively little impact on the MCP payment. That has significant implications for the ability to develop a predictive model that would reflect actual physician inputs that are required for the individual patient.

Finally, there are a number of policy and administrative implications that --

Brady?

CO-CHAIRMAN AUGUSTINE: Actually, a better stand would be, almost no impact because either you bill the MCP and get paid in 2003 or you don't. And the only issue could be is maybe distance from the physician, like those patients in Alaska that may or may not get seen on a monthly basis. That's the only factor I could think of

that would impact MCP.

SPEAKER: MCP was designed that way.

CO-CHAIRMAN AUGUSTINE: Yes. One other thing I'd like to add that may be helpful here is the fact that the MCP represents -- and clinicians on the board can correct me if I'm wrong -- about 60-70 percent of a typical nephrologist income. So even though it may be strong at the macro level, at the micro level it has a huge impact on our practitioner's daily lives.

MR. BACHOFER: The largest component, the nephrologist payment, is actually inpatient going, which is outside the MCP.

MS. RAY: And that was my question. I guess I'd just like to know the relationship. You said MCP accounts for about 10 percent of all payments. If you threw in inpatient visits made by a nephrologist to dialysis patients, what would that number then be?

MR. BACHOFER: It's not under the MCP.

MS. RAY: I understand it's not under the MCP, but it is related to the care of dialysis patients.

MR. BACHOFER: I actually have a number from USRDS that sort of does break out E&M codes on an inpatient

and outpatient basis to physicians. I hesitate to ever quote those kinds of numbers from memory, but the number that Brady gave is I think a fairly accurate reflection of that. It's about a quarter again as much or a third again as much, if I recall those numbers correctly. I could look it up right now.

CO-CHAIRMAN RUBIN: Brady's number was 68 to 70 percent, is what the MCP represented.

SPEAKER: I think that's high.

SPEAKER: Seventy sounds high.

MR. BACHOFER: We don't need to --

SPEAKER: It might be 60 percent of outpatients.

CO-CHAIRMAN RUBIN: I would guess that the MCP and inpatient work is probably equal and outpatient consultation probably represents the rest. If I had to guess, I'd say 40, 40, 20.

MR. BACHOFER: Okay.

CO-CHAIRMAN RUBIN: I know one large group practice that that's pretty accurate numbers for.

DR. OWEN: If we're going to use, quite candidly, anecdotal data, what I would suggest is that we go to the Renal Physicians Association membership survey, where at

least you'll have a larger aggregate of anecdotal data.

CO-CHAIRMAN RUBIN: Absolutely.

CO-CHAIRMAN AUGUSTINE: I always put in my caveat, and I will be corrected.

CO-CHAIRMAN RUBIN: Anyway, let's go on. This data exists and we can recover it.

MR. BACHOFER: These are the data from the 2004 USRDS annual report, Table K-20. If you look at the E&M side of this -- this is payments to physicians; this is per year at risk -- the E&M payments to nephrologists inpatient are $396 according to this; outpatient is $23, so I'm a little puzzled by that.

CO-CHAIRMAN RUBIN: Could we go on? Because you have to really get into how this was done and what they mean.

MR. BACHOFER: Okay.

CO-CHAIRMAN RUBIN: But Dr. Owen's point is well-taken. The RPA does this for a living, and if we need the data, we have good data sources.

MR. BACHOFER: I think that the point here would be just that the MCP is just a component of the total amount of physician payments that we're dealing with.

From the point of the view of the data, this slide shows the total dollar values per month for payments for the various components of this bundle, if you will. This is essentially looking at the most expansive of the first set of bundles, Bundle 1D, and then it adds to that the MCP.

This is based on 2003 data for patient months with 1 to 20 dialysis sessions. It is for hemodialysis patients only and it is for those months that include no events, such as hospitalization, the start of dialysis, end of dialysis, and so on. So these numbers may look a little bit different from other numbers that you may see.

DR. LAZARUS: You use the term 1 to 20 sessions frequently throughout this. Can you tell me what that really means?

MR. BACHOFER: I can actually see if someone from tech or KECC could comment on that.

DR. TURENNE: There was a relatively small fraction of months in which the dialysis facilities were submitting bills, but no sessions were reported on those bills; on the separately billables, specifically EPO and some of the injectables and labs. It's not a large number.

We're talking a magnitude of 1 to 2 percent of months in which some services were being billed by dialysis facilities, but there were no dialysis sessions reported on the bill.

SPEAKER: The 20?

DR. LAZARUS: Well, I can understand less than 13 if you're not there for part of the month. But the number of people above 13 has got to be incontestably small.

MR. TURENNE: It's very small.

DR. LAZARUS: So why, the average number of treatments per month is 1 to 20? It's a misleading comment to me. If it's 13 90 percent of the time we ought to talk about 13.

MR. BACHOFER: I think our reasoning on it is that because we are looking at trying to develop the payment system, we want to minimize at this point the extent to which we are including data from claims that have actually been paid by Medicare. So in effect we want to try to get as representative a set of values for actually paid claims as we can. The zero claims look a little bit peculiar to us, the zero session ones. So for a variety of reasons related to that, we decided to eliminate those.

If you look at, again, the dollar values here, the composite rate per month is about $1,700. All of the drugs that we would be including are about $1,110 per month. Laboratory tests add another $107 to that. All of the other services provided by dialysis facilities are $16 per month, and the MCP payment is 250. So it's about two and a half times the amount of labs, but it's about one-quarter the amount of drugs. That's sort of an aggregate of how much money would you be sort of looking at.

The next question is how much variability is there within these various categories. What this slide shows is the various points along the distribution, if you will, for composite rate payments, EPO payments, and MCP payments. The green area reflects the intercortile range or is spaced from the 25th to the 75th percentile. So half of all patients fall within the green range. The bar that divides the green range is essentially the median for each of these. What you can see is that for the composite rate you have a median value that's relatively small, about 5 percent variation on either side of the median value. Beyond that, the patients who are between the 5th and the

25th, 75th and the 95th percentile add some variation to that. But, again, it occupies a very small range.

For EPO, in contrast there's a very broad range of variation across patients in the intercortile range around the median value of about $500 per month. Bouncing down to the MCP payment again, it looks much more like the composite rate. In fact, it shows a little bit smaller amount of variation than the composite rate but not a great deal. The reason for the differences is simply a scaling effect, and if you show that as percentage terms, you actually can see that. In both cases of composite rate and MCP payments, 50 percent of all patients are varying by less than 5 percent on either side. In contrast, if you're looking at the EPO payments, half of patients fall between $240 and $950, so over a much broader range.

DR. LAZARUS: The variation in the composite rate is related to exceptions?

MR. BACHOFER: Actually, I believe the variation in this is partly exceptions and partly variations in wage levels and labor across areas. These are, by the way, payment on the composite rate, not cost data on the composite rate. So the only thing going into it is

basically labor, exception.

CO-CHAIRMAN RUBIN: Is that true for the MCP as well, that it's payments?

MR. BACHOFER: It's payments.

CO-CHAIRMAN RUBIN: So it's 80 percent.

MR. BACHOFER: No, I believe we inflated for the 80 percent. I believe we added that back in. So it's the total amount before cost sharing. It's what we call MAC, maximum allowable --

CO-CHAIRMAN RUBIN: Okay. So it's what it says on the slide.

MR. BACHOFER: Yeah. I'm plagued by the terminology on that.

So that's sort of the picture. One of the implications of this is, again, that identifying patient characteristics that account for no variations is going to be difficult. That just reflects the major data that we have available.

There are a number of administrative issues that come up under the MCP payment, the first of which is simply who would be paid for the MCP payment. A bundle payment would be made to the dialysis facility, arguably, but

receives the composite rate. The facility would then pay the nephrologist or other practitioners who are responsible for directing the patient's care. Other providers that are maybe involved in providing care would have claims denied. They may then come back to the dialysis facility and be seeking to have payment made for services that they believe that they would be entitled to have payment made for under Medicare, but it would have to be a coordination of claims processing between the dialysis facility, which becomes a claims processor in a way, and the Medicare administrative agent. The facility would then need to determine for any incoming claims which are payable and which are not and handle the disposition of it.

Secondly, there are a set of legal questions and regulatory issues that arise. Although there is a historical precedent in the program for paying nephrologists through the facilities, through the so-called initial method, it is our understanding -- and anyone can correct me on this; I would appreciate it -- that no one is being paid according to the initial method today. So while there are program instructions and there are provisions available to implement such a payment method, it is in fact

not used.

It also has a number of rules that go along with election of the initial method, namely that all of the nephrologists -- and this is the language of the manual -- "of the facility," whatever that might mean, would have to elect that method. If any one physician were to elect to be paid directly, then it voids the election for all physicians.

Outside of the initial method there are significant questions that arise, not that they are necessarily irresolvable, but they are questions that have to do with fraud and abuse and other issues in the Medicare program, which I try not to deal with as frequently as possible because it gives me a headache.

Third. Bundling the MCP payment would potentially result in the loss of information and there are impacts on data collection. If we are simply having an amount that is bundled into the payment, the question is what additional information would we need to be capturing on the claim to track things like actual resource use that might go along with that. We could either lose information or we would have to add additional information into the

claim.

MR. CANTOR: Henry, on that point are you referring like, for example, you would lose the number of times that a physician sees the patient?

MR. BACHOFER: Potentially. That is one potential effect unless the payment system specifically included adjustments for that. Of course, the notion behind a bundled payment system would be to start moving away from such requirements.

CO-CHAIRMAN RUBIN: Henry, is it fair to say that the last bullet, "impact on data collection," would be true for any components in a bundled system?

MR. BACHOFER: It would be a consideration in any such system.

CO-CHAIRMAN RUBIN: So it's a broader issue that this committee is going to need to deal with in its totality.

MR. BACHOFER: Right.

CO-CHAIRMAN RUBIN: Thank you.

MR. BACHOFER: We'll come back to the implications in a minute, but we'll move on to vascular access.

In a nutshell, the opportunity that it represents here is that we have established -- speaking somewhat personally, I have never seen such clear data related to the importance of vascular access on both cost and quality in any area in any medical studies that I've ever looked at. I've just sort of become acquainted with this, and I am hugely impressed by the ability of the people to demonstrate quantitatively the effect of alternative methods of vascular access on both cost and quality outcomes.

The notion here that including vascular access costs in the bundle creates a potential opportunity to positively impact both quality and cost is fairly persuasive. However, the number of issues that arise and the complexity of saying well how do you go from trying to encourage it through this method to actually designing a payment system that will do that are fairly substantial.

There are, first of all, a large number of players in this arena. They are dialysis physicians, vascular access surgeons, other physicians, hospitals and other facilities who are being influenced by the payment system which would be affected by such a bundling thing,

not to mention patients. So there are varieties of incentives that operate across those individuals and there's also coordination that has to occur across all of those parties.

There's also significant issues of timing that are involved in terms of when exactly would you start making payments for vascular access related services. Vascular access may precede the point at which the patient is actually under the care of the dialysis facility, and if you've bundled the payment into the dialysis payment in effect, you have no way of paying for that component of services.

There's also a timing issue that is related, which is vascular access procedures and costs tend to be rather lumpy. That is to say they are episodic in nature. They are large when they occur, and if you are bundling something into a payment system, then the question arises, how do you make that adjustment? Do you spread the costs of the procedure over all months in which the patient is receiving dialysis or do you come up with some method of actually providing large modifications or adjustments to payment amounts in those months in which a large vascular

access procedure or major procedure occurs. So there are complex issues that arise, complex economic incentives and then interaction with other policies, such as payment for other services, eligibility and coverage.

I've already commented briefly on the analytic problems that we have. It is very difficult to identify components for vascular access. It does involve both inpatient and outpatient surgery or inpatient and outpatient claims. It involves an extensive set of imaging and other ancillary services. It involves the rules that affect unbundling of surgically-related services. In other words, this is a significant issue for paying such a claim. When a claim comes from a provider that should be bundled with a surgical procedure, it would have to be routed back into the bundle that's going to the dialysis facility and it would have to go back to the facility to be paid.

Finally, there is this problem of identifying services related to maintenance of access.

DR. EGGERS: Henry, if I could just make one comment just about the episodic nature.

MR. BACHOFER: Sure.

DR. EGGERS: The farther you go away from the fee

for service and the more you go to a larger bundle service, the more episodic kinds of things you have and the need to sort of average across that sort of thing. I guess personally I don't give a huge amount of weight -- among the things you listed as problems of vascular access, I think the episodic nature is sort of not quite so critical.

MR. BACHOFER: I think that that's actually a good point. There are two issues, though, that I would draw attention to. One is that there is an implication of it for case-mix adjustment.

DR. EGGERS: Well, yeah, exactly. That was the other sort of point with that.

MR. BACHOFER: Right. The second is that even if you are then averaging under cost, you've got the problem of recovering the cost of the procedure, particularly for patients that may have to have repeat procedures and so on. It's not a huge, in a sense a fatal, problem, but it is a very different view of how to make the adjustment.

DR. EGGERS: The unfortunately good aspect of vascular access is though it is episodic, it's not unbelievably rare.

MR. BACHOFER: Right.

DR. EGGERS: It does happen frequently to a lot of patients.

CO-CHAIRMAN AUGUSTINE: Henry, let me ask a quick question. I take it we would not be able to tease some of these activity services out of DRGs. We've seen an increasing trend of vascular-access services being provided in the outpatient setting. By presenting a bundle, could that end up driving more care t go back into the hospitals? Would there be a financial incentive to do so?

MR. BACHOFER: I was actually going down a different path.

DR. EGGERS: I guess I would think it would be the opposite, wouldn't it? I mean, if you've got a fixed amount, it's clearly cheaper to do it in the outpatient side. Any organization that got a bundle for vascular access is going to look to buy it at the cheapest place.

CO-CHAIRMAN AUGUSTINE: That's if they know that it's being done in the hospital, if you can tease it out.

DR. EGGERS: Well, yeah. Then you have the problem of other providers and other players and stuff. The coordination with the real long list of other providers and actors that he listed just a little bit ago sort of

complicates it. But if in fact a facility or provider was responsible and you could assure somehow or another operationally that all the vascular access activities were going to be done through their organization, we'd be getting up to 90 percent on the outpatient side.

MS. GREENSPAN: You would have a procedure code so that all those procedure codes couldn't be by hospitals anymore because they had to be picked up. Of course you have a problem because there are people who are not parts of facilities --

DR. EGGERS: Well, that's the operational side about how --

MR. BACHOFER: How would you do it, right.

MS. GREENSPAN: So slipping them in is the issue here.

MR. BACHOFER: One of the issues would be if a person were to be admitted for inpatient service, it would mean that -- I don't know of any other example of an inpatient service that then becomes paid except under the inpatient payment system. In effect, the hospital has to then have a significant alteration in how they are approaching the billing for those services.

DR. LAZARUS: Is there any consideration anywhere in here that this will cover patients prior to dialysis?

MR. BACHOFER: Well, we may come back to that kind of a question. That's part of the broader policy issues that arise. I mean, we have no ability to extend entitlement to people who are not presently entitled to Medicare benefits.

DR. LAZARUS: That's being done in other areas.

MR. BACHOFER: They're looking at those kinds of questions, yes. The issue here of course is that about half of all Medicare ESRD patients are apparently already eligible for Medicare at the time that they develop end-stage renal disease. So at that point there would be something you might be able to do. But with respect to policy issues for patients who are not yet Medicare eligible, there would be no way that we could actually cover those.

DR. LAZARUS: If that happened, though, would that be included in this bundle? Is that a consideration?

MR. BACHOFER: It could be if we were to go that route.

CO-CHAIRMAN RUBIN: Assuming we decide to include

vascular access at all.

MR. BACHOFER: The issue that we then come down to is because of this difficulty of identifying components, I would love to be able to punch the button and have the next slide be the distribution of vascular access cost, but unfortunately we can't do that. While I may be going a little bit far on this, I think that what we discovered is that while it may be possible to actually quantify all of the precise cost that might go into a vascular access proposal, we might still be doing that at the end of the first year of the demonstration if we would just start to do it now.

In other words, it is a major analytic challenge to begin pulling together all of those data and develop the definitions of all of the components that would need to go into a bundle, and then try to say, well, okay, what do the actual costs look out for what would we be dealing with here and what would the implications of that be for who would be billing whom and paying whom within the system. So at this point we sort of had to cut our losses in terms of availability of time to actually generate data and say is it really worth going down that path.

Bob?

DR. WOLFE: Henry, I'd just like to say that there are some other groups who are working on this issue of trying to look at vascular access costs based upon DRG codes. There are panels. Bill McCullen is working with one. USRDS has done a lot of work with this. We've done a lot of work with this.

It's not impossible to do. I will say that there is going to remain ambiguity about certain decisions no matter what you do. I think that coming up with an average vascular access cost will depend upon who does it and what assumptions they make when they come up with that. There can be quite a variation in the number that you come up with, depending those assumptions. I don't think any one of them can be labeled as the goal standard; they're just decisions.

MR. BACHOFER: That actually provides a segue into the real problem. So while we would like to look at some data on the costs, you really come back to some of the policy and administrative implications of trying to implement this on the kind of time frames that we have to work with. And those are specifically not so much deciding

the dollar amount to be added into the payment. In effect -- and I don't mean to dismiss this -- that's in a sense the easy point. The more difficult part is how do you write all of the rules that go along with processing all of the claims that would be submitted by that large number of facilities so that they can actually not end up paying twice for services that should be paid through the bundle. And then how do you go about implementing all of those changes throughout all of the claim systems that Medicare currently uses to pay for each of the component parts of that. Not to mention then from the facility point of view, what kind of administrative burden is being imposed on the facility as they be gin having to process and respond to claims from a large number of providers that they're not currently seeing.

There are a variety of issues that have to do with coordination of payment systems, both inpatient and outpatient and so on. There are policy questions dealing with what kind of adjustments would need to be made, what kind of case-mix adjustment would be need to be made, what kind of policies do you have for repeat procedures and so on.

MS. CUELLAR: Where does patient choice fall in here, where the patient chooses not to use the surgeon or the interventional radiologist?

MR. BACHOFER: I think that's also a good point. In effect, you're moving towards a kind of managed care kind of a system that has a partial capitation, a feel to it. That actually is an interesting point. I'm surprised I didn't include that. But, yeah, I think that's an excellent point.

The bottom line is essentially that while the concept of broadening the bundle to include these services certainly has much to recommend it, at least at a conceptual level, the actual practical problems of implementing it are at this point in time something that sort of moved the proposal from let's do it now to let's think about how we might do it at some point in the future, at least in our minds.

The data on MCP payments also highlight some of the technical problems that we would have in trying to figure out how much to include and the ability to appropriately adjust amounts under any kind of a bundle payment system. The vascular access problems with the data

there indicate the magnitude of the problem with simply figuring out the amount, first of all, to add on, and second of all, how to define that in such a way that it's administrable. And then there are a large number of complex policy choices of which Paula just actually highlighted a new one.

As we look at this, we think that there are a number of issues that the proposed incorporation or expansion of the bundle to include these services touch on that we can get out through P4P or some of the discussion under that part of the agenda, and so we probably will come back to that; is there a way of using P4P to encourage more appropriate vascular access procedures; is there a way of using P4P to encourage greater coordination between physicians and facilities and so on, which was really what the goal was to begin with.

So at this point in time what we would sort of like to do is very quietly sort of put this particular notion of bundling these services into the bundled payment system to rest and sort of say let's not spend any more time trying to figure out what we would do with this. Any comments?

CO-CHAIRMAN RUBIN: Well, we'll formally get to that issue this afternoon. That was an excellent summary of some of the issues that are important in thinking about that.

Does anyone have any general comments? Paul?

DR. EGGERS: Well, yeah. I guess I'm less concerned about the limitations of historical MCP data as a reason for doing this because this whole exercise is kind of premised on the implicit assumption that whatever's going on in the real world in the most recent year is truth or the right thing, and we are using that level as our starting point to reallocate some other way. Had we done this five or six years ago, there would be a different mix of services, different uses of EPO and so and so forth; people were doing what they thought was right five or six years ago; they're doing what they think is right now, and so and so forth.

You've got a certain policy change that hasn't been allowed to be around long enough to be incorporated into our version of truth, but you can always be that way. In every single time in which you're using real-life data and saying, okay, we're going to allocate those same kinds

of resources, we have to implicitly assume that.

Now, I fully agree, though, on the complexity of these sorts of things, sort of a bleeding in evolution rather than revolution in terms of payment policy. I tend to lean towards doing things you can do well as opposed to trying to change.

CO-CHAIRMAN RUBIN: Okay. We're a little bit ahead of schedule. Unless there's objection, what I'd like to do is push forward with the next section for 30 minutes, and then we'll take a break. You and I and Brady will all keep eyes on our watches, and then in 30 we're going to shut you down for 15 minutes.

MR. BACHOFER: Okay, that's a deal.

CO-CHAIRMAN RUBIN: We'll let you moisten your throat because you've been talking almost non-stop.

MR. BACHOFER: I apologize for that.

CO-CHAIRMAN RUBIN: You've been doing great.

MR. BACHOFER: All right. This next section, we'll sort of shift focus a little bit. Instead of looking at those two broadly expanded bundles, we'll be looking at the descriptive data for the more narrowly-defined bundles, 1A through 1D.

CO-CHAIRMAN RUBIN: For those on the committee, this is Tab F.

MR. BACHOFER: Tab F. I attempted in this to somewhat summarize the 151 pages of tables that also were inflicted upon you.

The goal of this presentation is to just touch on the general framework and review somewhat the nature of the data that we're using in this analysis, highlighting some of the limitations or implications of those limitations for the numbers that you'll be seeing. We also are going to look at some of the implications of those data choice of bundles. Again, the goal here is to try to focus on the statutory charge of what should be in this bundle.

Here what we're looking at are these first four bundles. We will be in this case working from the bottom up, going in a sense from Bundle 1A, which is the most narrowly-defined bundle, up to Bundle 1D. I think I've already been through the definitions, so I'm not going to take time to do it again.

Again, the policy criteria that might be applied in thinking about each of these bundles are outlined here on this slide, again, pulling from the IOM reports on the

quality chasm series. What kind of opportunity -- at any given stopping point along that continuum of narrow range, as we'll see -- does that afford to promote safety, promote effectiveness, patient-centered care, timeliness of care, efficiency and so on? To what extent does stopping at various points or moving beyond a certain point on that continuum potentially create risks in each of those areas?

Unfortunately, we don't have a good set of measures defined for each of those that would allow us to quantitatively say, okay, what is the effect of this bundle on safety? That's much more of a judgment call, and that's actually the hard task that I think you all have, is to sort of say, given what we know at a more knowable level of what we can know about these data, what do we think the implications of moving to various points along this bundle would be for things like safety, effectiveness, patient-centeredness and so on?

What we'll be primarily focusing on at a quantitative level in this are questions like, what is the size of the bundle, what is the impact of moving to one of these definitions or adding a particular set of services into the bundle? What is the impact on the amount of

resources that we're talking about, the total payment amount that we're looking at, or maximum allowable charges as the case may be?

Secondly, what do we know about the amount and nature of the variation within that set of services, both among patients? Keep in mind that at another level we may be as interested in variation across facilities as we are across patient level data. We'll come back to that. I'll talk about that much more extensively I think.

Finally, based on those more quantitative questions, we'll try to look at some of the implications for patient selection or access issues for the kind of financial risks that a facility is being asked to assume under one of those kinds of bundles; implications for case-mix adjustment, and more specifically I think, for the kind of work that a case-mix adjustment might be asked to do under one of these systems; and implications for the unit of payment that we might adopt.

Again, just to refresh everyone's memory on that, we sort of had proposed at the last meeting that there's sort of two choices here. One is a session-based payment system and one is a month-based payment system or payment

per month. They both have some attractive features to them and they both have some risks and deep, unattractive features attached to them. We're trying to look at these data to say what does that tell us about what way we might want to go on the unit of payment.

CO-CHAIRMAN AUGUSTINE: Henry, one last point is that there will be cost-sharing implications for our beneficiaries. Some patients will pay more and some will pay less in any type of expanded bundle type environment.

MS. RAY: Why? For drugs and the composite rate, it's 20 percent, right?

DR. EGGERS: If you're a patient and you're not an EPO user.

MS. RAY: Yes.

CO-CHAIRMAN AUGUSTINE: And if you use less than the average, then you may end up -- because the whole payment's going to be based on the average. So depending on where you fall on the distribution, you may pay more or less.

MS. RAY: Yes.

DR. LAZARUS: My understanding is that facilities that participate in this demonstration will be all the

patients in the facility. Everybody in the facility will have to participate in the demonstration. Is that correct?

CO-CHAIRMAN AUGUSTINE: We have started to think through the question of what are the rules for people participating in this. Our assumption at this point in time is that this is facility-based demonstration. It's not like a managed-care demonstration in which people are, in effect, by enrolling in the demo, limiting their access to providers. Therefore it would be operating on a facility basis, but there are obviously issues that need to be worked out there and we will be taking up actually at our next meeting.

DR. LAZARUS: I cannot conceive medically you could do this any other way.

MR. BACHOFER: Right.

DR. LAZARUS: I don't see how you could split patients and put half of them into this demonstration and half not. I can understand that from a managed-care case risk, but not this bundle, I think to manage that dialysis unit.

CO-CHAIRMAN RUBIN: I can tell you from running this by the legal beagles at the department that we're

going to need to be talking to them about this because you cannot compel a patient to join a demonstration. Unless the rules have changed since I've been around, you absolutely cannot do that.

I think your point's right on, but it's a distraction for which there will be an empiric answer.

DR. LAZARUS: And the empiric answer is not at this table.

CO-CHAIRMAN RUBIN: For sure.

MR. BACHOFER: I was going to say not at this meeting. But, yes. It's an issue that we are aware of. That's the only point I want to get across. As pointed out, it's something that we know there are some legal questions that are involved and will have to be dealt with as we go forward. Having said that, we're also sympathetic to how do you work something like this work if they're splitting it up, which is also a significant research and demo question.

Very quickly reviewing a bit on the nature of the data here just to sort of, again, orient everyone. The primary data sources that we are using are the enrollment files, and most importantly the Medicare claims files.

There's also some data I believe that are pulled in still from the Social Security Administration, but there's relatively small use of those data made in these analyses that you'll be looking at. Primarily I believe it's on identifying -- within this population.

The characteristics of the billing or claims data are important to keep in mind as you go forward. Bills are generally submitted on a monthly basis by a provider, so in effect what we have are monthly claims records. We do not have information on individual sessions. Those claims records include counts of sessions, but we do not have specific information that attaches specific resource use to individual sessions. So our primary focus here, and what I'm going to be looking at as we go forward, is on monthly data. I'll have a caveat on that at the end. But in anticipation of that, I'm looking at the month primarily to get a feeling for what's the total resource use over a month for a patient, rather than to make a presumption that we would pay on a monthly basis. Rather than looking at what are the resources attached to an individual session, just a little bit broader focus on what is the resource use over the span of a month for patient.

The data have been aggregated in various ways. We've aggregated data from multiple sources or multiple providers. For example, the laboratory data that you'll be looking at include laboratory bills from both the dialysis facilities or hospitals, as well as from "independent or freestanding labs," including the labs that are affiliated with, in a corporate sense, the dialysis facilities. So we've essentially aggregated things up to the individual patient and to the patient month, and then have combined bills across providers to create a patient month record. Essentially the primary unit of analysis in this is in a sense the patient month, although we report the data and the detailed tables on both a per month and per session basis.

There are a few more caveats on the data. These obviously represent patterns. In 2003 I would second Paul Eggers' comment of a moment ago; this is sort of what we've got. But it is important to realize that it does not reflect in payment policies, it doesn't reflect any behavioral response for those payment policies, and going forward in time, it doesn't reflect what the potential impact would be of implementing Part D under Medicare or

any other payment changes. Again, we can't forecast that at this point in time, so you do what you can, but it's something to keep in mind in interpreting the data.

There are a couple of implications using these data, which I would simply note. How much of an impact do those limitations have on various uses? First of all, we are primarily using these data to evaluate possible bundles. What we're primarily interested in are, in a sense, order of magnitude, kind of are we adding a lot of money into the bundle, a little bit of money into the bundle. We're also interested in how much variation is there within any particular category and how does adding a particular class of resources increase or change overall variability across patients. Probably the limitations of the data have a relatively small effect on that.

Secondly, we're using these data to assess alternative payment models and in particular this question of per session or per month. Again, the limitations of the data probably have a relatively negligible effect on that kind of interpretation.

Thirdly, we're trying to use these data to look at the feasibility of and potential effectiveness of

alternative case-mix models. While there can be some impact of these limitations on the exact amount of adjustment that you might make for a particular patient with particular characteristics, overall, in the big picture, there's probably relatively small differences in the overall picture that emerges about the feasibility or effectiveness of alternative ways of adjusting the patient characteristics.

Finally, I would just urge everyone to keep in mind that the numbers you are looking at are not what you'll see when you calibrate a payment model. In other words, the dollar amounts that are here are not the dollar amounts that we would paying under his demo. That requires a different kind of analysis which requires you to do some calculations to make sure there is not an increase or decrease in total payment against the payment benchmark. So in the specific adjustments and so on that come out at the other end of this, we undoubtedly differ from the dollar amounts that are shown here, but that's just the nature of the payment model and the payment simulation.

Finally, I would simply note that, unfortunately, despite all of these limitations, these are the data that

are available. You have to use what you've got, and Medicare has to do that day in and day out as we development any payment system.

Another caveat concerning the 50/50 rule is there has been a fair amount of discussion at laboratory billing because of course we're looking at laboratory tests. People continue to raise appropriately the question of, what impact does a 50/50 rule have on these data?

My somewhat simplistic version of the rule -- and many of the people around this table have a probably far greater technical understanding of what the actual impact of the 50/50 rule would be than I. But for those people who aren't that familiar with the 50/50 rule, it essentially is a rule that applies to the 22 automated, multichannel analyzer tests. What it says is that for all tests furnished on a single day, that you may be paid for it, or they bill for those tests, only when 50 percent of those tests would not otherwise be bundled into the composite rate.

I think I said that correctly. If I didn't, please correct me. On the other hand, more than half of the tests that were performed on that day -- of those

multichannel tests -- would have been paid and, hence, bundled into the composite rate under the rules that apply to laboratory tests for the composite rate, but none of those laboratory tests are payable.

The effect of that is that the data do not, for a couple of reasons here, reflect the actual use of laboratory tests. When you see numbers like $75 worth of laboratory tests in a month, that does not reflect all of the laboratory tests that are performed on behalf of that patient during that month. It only reflects those tests that were billed during the month. So it doesn't include any of the tests that were bundled into the composite rate, and it doesn't include any of the tests that were disallowed in effect by the application of the 50/50 rule.

I indicated here that the 50/50 rules goes into effect in 2005. It actually has been in effect for quite a while. There are some issues that have to do with enforcement and implementation of systems changes for carriers that do not go into effect until 2005. But the rule itself has been there and, in fact, dialysis facilities. And so the billing data that we have here reflects whatever degree compliance facilities have had and

laboratories have had with the 50/50 rule up to this point in time.

Finally, what is the effect of bundling on the 50/50 rule? This was the point in which I saw a couple of people's eyes light up. Generally, it would make the 50/50 rule moot. It would make it go away in effect because all of the lab tests would be bundled into the payment, so therefore there would be no need to evaluate individual lab tests to determine whether or not they would be billable.

There are some issues that then arise as to how much of an adjustment would need to be made to payment amounts under that question of calibrating the payment model -- how much of an adjustment would need to be made to payment amounts to reflect the operation of the 50/50 rule -- but those are more technical discussions that we'll get into at a later point in time.

MR. CANTOR: Do you have any estimate as to what financial impact the 50/50 rule has had so far on this data?

MR. BACHOFER: I do not. We're looking at developing some of that information. Anyone who has information that would help us get a handle on that, it

would be very helpful to share it with us. I have phrased it in a couple of instances that it's sort of like the bird watchers guide, the Peterson Guide. Are we talking about something that's larger than a robin or smaller than a bread box? I don't know. Are we talking $5 per month; are we talking $50 per month? That's what we're sort of trying to get a handle on.

Brady has indicated in conversation that based on past discussions of the 50/50 rule that probably the majority of multichannel tests are disallowed under the 50/50 rule. But whether that means 70 percent, 80 percent or 55 percent we're not really sure at this point in time, but we're continuing to try to get a handle on that.

CO-CHAIRMAN RUBIN: And we feel pretty good that we can get a handle with the help of the dialysis-associated labs. Several people have indicated willingness to share that information with us. So I think that from a technical perspective, whether it's 5, 50 or whatever the right number is, we can plug the right number in, and from a policy perspective we shouldn't be concerned that we're going to miss that. In talking to people that was the general consensus.

CO-CHAIRMAN AUGUSTINE: A lot of the foundation for this work has already been done. We've had some interactions with the community, CMS for the lab tests frequency project. It was initiated I think two years ago and received some input from the community in 2003 that would be a good starting point if we need to reach out to the community again to get some better information.

MR. BACHOFER: Another caveat on the data that I would just draw your attention to is that any of the data that we have sent out in those extensive data tables and in the reports on the descriptive data include no adjustment for case mix. I know that's noted in all those reports. These are essentially raw data in a way that describes variation across patients. It's the aggregate amount of variation that occurs. It has made no attempt to correct, if you will, for patient characteristics. It's sort of preliminary to that, if you will. In a way it suggests the amount of work the case mix may need to do, if you will, meaning that will become apparent.

The purpose of case mix is to really get at and sort of parse apart the three principle causes, if you will, of variation and costs among patients, those being

differences in patient needs or response to treatment; variation in treatment patterns that is unexplained by need; and variation or differences in provider efficiencies, simply how good is a provider, if you will, at producing lab tests, sort of dialyzing patients, what kind of resources go into an episode of treatment.

Case mix is really an attempt to get at the first of those characteristics; to pull out of the overall variation that part of the variation that is attributable to patient needs. The question in effect we're all left with and that Bob and everyone else we will be talking about later is what accounts really for the remaining variation and what's significance should be attached to it. How much of the residual variation -- the variation we can't account for in a case-mix model -- is really unexplained differences in patient need, that we haven't been able to measure, and how much of it is really a reflection of underlying differences in treatment patterns or efficiency? Unfortunately that becomes a judgment call at this point.

Finally, I would note that all of the numbers that you're going to be looking at focus on patient level

variation. Obviously, facility level variation will be less because each facility doesn't treat a completely unique group of patients. There's a lot of similarity across facilities and the mix of patients that they treat. Much of the between patient variation sort of averages out when you take it down to the level of a facility. Again, this will come up later on, particularly in a case-mix discussion where there will be some discussion of what do we know about the ability of case-mix measures to account for interfacility variation and use of these separately billable items.

I would simply note here that simply relying on averaging occurring at the level of the individual facility does still leave unaddressed the question of how much of an opportunity is there for patient selection. Even if all facilities treated an identical mix of patients, so that there was no interfacility variation that could be attributed to case mix, variation at the level of the individual patient still leaves an opportunity for facilities to select patients that are in effect more or less more profitable or penalized by having patients that are more expensive than average.

So the level of variation at the individual patient level still remains an issue when the issue of selection -- and going back to some of those criteria -- the issue of equity in particular comes up, but also the issues of effectiveness. We'll be coming back to that.

MR. CANTOR: Can I ask one question?

MR. BACHOFER: Yes.

MR. CANTOR: On that variation point, several times I've seen this term "outlier" used. How would you statistically calculate an outlier? For any particular patient whose total costs run up above a certain amount, could a facility cry uncle or get a bonus or something like that? Not a bonus, but compensated.

MR. BACHOFER: When we get into the development of the actual payment model, which is really what we will be coming back to in the third meeting, one of the issues that we will have to take up and we'll be discussing some I think this afternoon, is the question of what evidence is there here in these data that we need an outlier policy? If we do need an outlier policy, how might such an outlier policy work?

When you start talking to people about outlier policies in any pair, including Medicare, people start getting extremely nervous because they're actually very difficult in many ways to design and implement, or can be. You have to be concerned about exactly what are the definitions, how many patients do you want to have included, and how do you calculate payments. Many of the Medicare's payment systems, for example, don't include outliers, but some of them do. The hospital inpatient system does include outliers. We'll be coming back to that question of how would you define them, what evidence is there of a need for them, and how do you implement such policy.

MR. BACHOFER: Finally, I've already commented on this, but just to remind you, the data that I will be presenting here are primarily per month, not per session statistics. The case-mix analyses that you'll be looking at will tend to be emphasizing more per session stuff, although there are some case-mix analyses that we'll look at per month as well.

Again, it's an arguable perspective perhaps, but my goal in doing this is to sort of focus on the question

of overall research requirements for a patient over the course of time, for a patient with a chronic condition. I wanted to sort of look at a big number, if you will.

Secondly, services are -- for many of the separately billable items -- not necessarily or as strongly related to the session as the composite rate stuff are, although that's certain an artifact of the way the payment system operates. There's no presumption in any case at this point that we would be going in one direction or the other if you look at these data. That's a question that we'll come back to and talk about this afternoon.

DR. LAZARUS: As you calculate this, there are a lot of services that are provided more infrequently than monthly. What was the base of time you took to get your monthly average? A year?

MR. BACHOFER: No. These are actually claims submitted during the month for services provided during the month.

DR. LAZARUS: But some months are going to be different than other months.

CO-CHAIRMAN AUGUSTINE: Henry, he's saying what was the total aggregate period that you took to come up

with these months. We've looked at 2003 data.

DR. LAZARUS: For a full year, 12 months.

MR. BACHOFER: I think we have two different perspectives here. One way of coming up with per-month data would be to look at patients average use of services over the course of an entire year, and basically divided by 12.

That's not what we did. What we were doing were looking at individual months for services rendered during the month. Then we aggregated up to the services for that patient that were provided during the calendar month. The number of days included in the month is variable. Some months have 31 days; some months, February, has 28 days.

CO-CHAIRMAN AUGUSTINE: Mike's trying to make the point -- there's some cases that are only done once annually, quarterly, and they would be --

DR. EGGERS: Yes. But if you take 200,000 patients, even if you only took one month. 10,000 of them would have whatever that rare thing is or 50,000 of them.

DR. LAZARUS: Well, I don't agree with that. A lot of thing are done on calendar year at the end of the year. So December is going to be decidedly different than

June.

DR. WOLFE: So to the extent that things happen on an annual cycle at least, recapture the things that typically happen once a year and that happen quarterly. When we look at it on a per month basis, it will be one-quarter of the frequency at which it happened on a quarterly basis. If it only happens in April, we'll spread it across the four months and say it happen .25 times per month, when in fact it went per quarter.

DR. LAZARUS: So you took a quarter average instead of a year.

DR. WOLFE: We did take the full year.

SPEAKER: We did take a full year.

DR. WOLFE: They did take the full year.

MR. BACHOFER: We have the patient's total experience over the course of the entire year. But in this example, if the tests were performed in April of every year, those costs would all go into April. In these data they would not be spread across multiple months, but if we were to calculate an average per month amount --

SPEAKER: That's correct.

MR. BACHOFER: Right.

CO-CHAIRMAN RUBIN: This seems like a good time to take our 15-minute break. Everybody should fortify themselves because now we're going to put a lot of numbers on the table and we're going to talk about things like variation and all sort of arcane things like R^2 and stuff like that. Why don't we reconvene at 10:45 like the schedule says.

(Whereupon, there was a brief recess.)

CO-CHAIRMAN RUBIN: Okay. Before we resume our presentation, I would like to note that we're going to have a sheet after lunch. People who would like to make public comments, sign the sheet so we have some idea how many people at least at the lunch break plan on making public comments so we can try and allocate an appropriate amount of time for that to occur. I would appreciate it if the public members who are in the audience would please take this opportunity to do it when we break for lunch.

CO-CHAIRMAN AUGUSTINE: In fact, I'll leave it at the table outside so you don't have to come up here and sign it. It will be available to you if you'd like to use it.

CO-CHAIRMAN RUBIN: The other thing that I wanted

to mention as a housekeeping matter is for those of you who don't already know, there is a lot of information that may amplify what's been presented today on the website that this group has. For those of you that want it, I'll write it later. But it's www.cms.hhs.gov/researchers/demos. We're the ESRD bundling demo. As they say on the airplane, if you're not here for that, you probably ought to check your ticket.

Henry, can you continue?

MR. BACHOFER: Thank you. As Bob said, now we start looking at the numbers here. I'll also, Bob, put up the Web address at the end of this afternoon session so people will be able to get it.

CO-CHAIRMAN RUBIN: It looks like I was giving somewhat flawed data.

MR. BACHOFER: Well, there are two websites is the problem. There's a FACA website for the committee and then there's a demo website. We actually will be putting most of the material for the committee on the FACA website or address.

CO-CHAIRMAN RUBIN: I stand corrected. I'll chastise my data source later.

MR. BACHOFER: The slide that's up now is a summary of the differences across the four bundles. It includes the composite rate component as well as the separately billed component for drugs, lab tests and other. As it is immediately apparent from looking at the figure, all four of these bundles, 1A through 1D, are remarkably similar to one another for reasons that will become apparent.

Before going any further on this again, I'd like to draw people's attention to the fact that this is based on the 2003 data. It's months with 1 to 20 sessions. It's four months only for hemodialysis patients. That is to say it does not include months in which events occurred to interrupt the usual course of three times a week dialysis. That will not be true on some of the subsequent slides, that's identified on those slides, and I will draw attention to that. In other words, there are slight differences in the populations that are used.

Essentially what this shows is that in all bundles the composite rate accounts for 60 percent of the total, 58 percent to be more precise or $1,682 per month. Bundle 1A, which adds EPO, iron and Vitamin D and the

related labs, adds $1,146 per patient month to the composite rate, and those services account for 90 percent of all additional separately billed amounts that would be added under the most expansive, Bundle 1D.

In other words, when you're looking at Bundle 1D, you're essentially still looking at largely the pattern of variation and particularly as we'll see for Bundle 1A because it is the EPO particularly, but also iron and Vitamin D that dominate the separately billed items and services. As I say, the slide makes it apparent that the dollar amounts are relatively constant or equivalent across all of those. Those people who sort of look at numbers, it's a little bit easier to see what's going on here.

The drug amount under Bundle 1A for those three drugs is $1,082 per month, labs add $64, and that's just the labs for anemia and Vitamin D. The total therefore becomes $2.828. Bundle 1C has a drug amount of $1,100 that includes the first three drugs. It only increases the total amount for drugs by about $18 per patient month, and it adds only $11 per patient month for the two categories of the lab tests that were added into the bundle, namely lab tests for infection and lab tests for carnitine.

Bundle 1C basically takes all of the remaining drugs and the extensive list of laboratory tests, and again it adds $10 per month for drugs for a total of $1,110, and it adds about $32 for labs, to bring labs up to 107. Finally, Bundle 1D doesn't add any more labs or drugs, but it does add $16 per patient month for all of the other services that dialysis facilities bill.

CO-CHAIRMAN AUGUSTINE: One important note in there is it would include, for example, blood and things of that nature, like transfusions, that are not included in any of the other bundles.

MR. BACHOFER: Right. The largest category in the other group is actually medical surgical supplies, which actually is slightly larger than the total amount in a directly-billed laboratory. But in percentage terms it accounts for 0.3 percent of total payments. It's a significant part. I haven't tried to split it out here into what components it would be, but medical surgical supplies is the largest category, followed by actually blood-related items and services.

DR. OWEN: Can somebody tell me what a medical surgical supply is?

MR. BACHOFER: 4 x 4 gauze pads.

SPEAKER: Syringe they use to inject EPO.

MR. BACHOFER: Well, I don't know, but it includes syringes, for example. It includes --

SPEAKER: Stuff.

MR. BACHOFER: -- stuff. I have to admit, I was sort of mystified when I started going this list of all these separately billed items. I said, why aren't these already part of the composite rate? But they're historically not part of the composite rate, so they're actually just sitting out there outside of it. One of the things that we may want to talk about under 1D is to what extent do we want to bring some of those items and services over into the bundle. The sort of ironic part of it was while we were looking trying to figure out what to do about vascular access, I kept looking at medical surgical supplies and going, but what about these? At any rate, that adds $16 for months.

You can look at that incrementally, and actually I already did this for you. But, again, that makes the point somewhat clearer. Those first three drugs -- iron, EPO and Vitamin D -- are really accounting for almost

everything in terms of that's being added in. The incremental amounts being added on, from going from 1A to 1B, adds only $29 per patient month. It adds only $43 per patient month to go from 1B to 1C. And it adds obviously only the 16, and only a part of that actually would be things like non-radiology purposes. So it's actually a relatively small dollar amount. Again, I recognize that as you multiply this by millions of patients, 2.9 million a month, these things have a way of adding up. Again, these are still for HD patients for four months only and not months that include any kind of events.

That's sort of a broad picture of the dollar values, the magnitude of the dollar values that would be added on. But the next question is what kind of variation do we see within the months? In effect, the issue of variation is what concerns us here, particularly as we get into case mix. It is the concern; to what extent can we account for variation?

This is perhaps not the most eloquent way of presenting this kind of data, but these are essentially percentile points for the 25th, 50th, 75th and 95th percentiles. As you can see in the figure, the

composite rate shows relatively little variation; we already saw that in an earlier slide. The 25th percentile is $1,578. The 75th percentile is $1,764, so that the total spread there for 50 percent of the patients is only $186 per patient month. Again, it's about 6 percent, or thereabouts, of the median.

DR. EGGERS: EPO.

MR. BACHOFER: EPO is in Bundle 1A.

DR. EGGERS: It's also in Bundle 1B, 1C and 1D.

MR. BACHOFER: In 1B, 1C and 1D. It's all the way across.

DR. EGGERS: That's why it is equal.

MR. BACHOFER: Correct, and it is equal.

CO-CHAIRMAN AUGUSTINE: That variation is consistent throughout all of them.

MR. BACHOFER: Well, it's the same, because it's the same dollar value.

But if you look at 1A, the 25th percentile is $2,229 versus the 75th at $3,163, so that you have an overall spread of $934, roughly twice what the median value is. So half of the patients fall within a range of about $1,000 on either side of the median and half of all the

patients fall outside of that range, either less or more.

As Paul Eggers just pointed out, because drugs are essentially dominated by EPO, all of the succeeding bundles look very much the same. As a result, expanding the bundle beyond 1A and adding in these additional categories of drugs really doesn't do very much to increase overall variability. By the time you get up to 1D, the difference between the 25th and 75th percentile is $969, only about $35 per month more than it was for Bundle 1A. So, essentially, variation appears to be substantially driven by EPO.

MR. CANTOR: Henry, in that regard, could that variation be attributed to the dose response for EPO?

MR. BACHOFER: I can't answer that question unfortunately, but we'll get into that I think as we get into the afternoon, and that's I think exactly the kind of direction we need to be going in.

CO-CHAIRMAN RUBIN: Actually, I think Bob, or whoever is going to make the presentation for Michigan, will talk to that issue directly.

DR. OWEN: Recognizing that you probably don't have the data because the number of subjects is too small,

does anyone around the table have a sense as to whether or not if you go to Sub Q versus IV EPO, you see this sort of dosage variability?

MR. BACHOFER: Could I ask actually that we perhaps hold that? It's a great question. We don't have data on it, but it's I think a great question. The reason I'd ask you to hold it is simply because we're going to go through the individual components of this.

DR. OWEN: I'll be a provocateur.

MR. BACHOFER: That's fine.

DR. OWEN: My sense from abroad is that this sort of variability is not the case when other labs of administration are used.

MR. BACHOFER: Okay.

DR. WISH: CPM has that data.

MR. BACHOFER: One alert to an issue here, the previous values were all looking at means. These are going to be looking primarily at medians. But also the population we're looking at has shifted somewhat. This is looking at all HD patients for all months and not simply pulling out those months with a full, regular, uninterrupted course of three times a week. Part of the

reason for that was to keep it consistent with the data that we had sent out earlier in April, which was really trying to look at sources of variation within the month.

If you look at the various components on injectable drugs, the first three categories here, EPO, Vitamin D and iron are all under 1A. What this is illustrating is that for those three category of drugs, the vast majority of all patients receive those drugs every year, so that almost 100 percent of patients receive EPO at some point over the course of a year. About 78 percent of all patients receive Vitamin D at some point over the course of the year, and just under 90 percent of all patients receive iron over the course of the year.

If you look at individual billing on a month-by-month basis, over 95 percent of all patient months involve billing for EPO, over 60 percent involve billing for Vitamin D, and over 50 percent involve billing for iron. Essentially what it appears here is that these are drugs that are used very consistently by the majority of patients, and I would characterize them I guess, for lack of a better term, as sort of chronic in their use.

The next three categories of drugs, which are

included in Bundle 1B, Levocarnitine, Alteplase, and Vancomycin, show a very different pattern. A minority of patients over the course of a year receive those drugs, although Vancomycin is used by about 28 or so percent of all patients. But Levocarnitine Alteplase are used by much smaller percentages. And strikingly, less than 5 percent -- for the most part, although Vancomycin shows a little bit higher -- of patient months involve those drugs. So again, although those drugs account for a relatively small amount of average added costs, when they occur they can add quite a bit to the cost for any given moment, which is the consideration I may want to come back to.

DR. LAZARUS: The difference between the yellow bars and the green bars reflects episodic nature?

MR. BACHOFER: The yellow bars here are the percentage of patients who at some point over the course of a year received one of these drugs. The green bars are showing the percentage of patient months that involved claims for those drugs.

DR. LAZARUS: And reflect episodic administration?

MR. BACHOFER: I would say yes. Offhand, what

we're seeing here is that Bundle 1A is generally something that's going on very consistently, month to month. The drugs in 1B are much more episodic in their character. At least for me, being the non-clinician that I am, it's sort of easiest to understand is for Vancomycin. You say, well, patients have infections. They don't have infections all the time. Some months they do; some months they don't. So it's much more episodic and acute.

The other injectables sort of occupy an odd middle ground where the majority of patients use them, but they're used much more sporadically or episodically so that on a patient month basis it's really 100 percent of patients.

DR. EGGERS: Do you somewhere give us a list of those other injectables?

MR. BACHOFER: Yes. Actually, if you look under Tab C, that's the easiest place to find that. On page 3, if you go down that page, under Bundle 1C, other injectables gives you the listing, which would be Hepatitis B vaccine, flu vaccine, and I'm not going to even try to pronounce the rest of these because I'm not a clinician.

DR. EGGERS: Page 3?

MR. BACHOFER: It's page 3 under Tab 3.

If we look at the percentile breakdown of these various categories, consistent with what we saw previously and as Paul Eggers pointed out, if you look at EPO, the 25th percentile is 240, the 75th percentile is 953. Again, you have them across a very broad range; you've got a significant amount of variation. If you look at Vitamin D, the 25th percentile is actually zero, so fewer than 25 percent of the patients are using it. The 50th percentile is 125 versus 301 at the 75th. So 25 percent of patients are using more than $301 of Vitamin D per month. For iron you have a similar pattern in that it's used by 25 percent of patients. More than 25 percent receive none in patient months, the median value is 66 and 75 percent of patients have usage at $204 or more.

The next category of three drugs, the Levocarnitine, Alteplase, and Vancomycin, oddly enough the first two are used by fewer than 5 percent of patients, so there are no percentile points on this chart, and only Vancomycin shows up it's being used by 5 percent of patient months or it's billed on 5 percent of months with an

average value of the 95th percentile at $14. The other injectables have a similar sort of a pattern. They're only showing up in 5 percent of patients. I think this gets actually to a point that was made earlier about some drugs, vaccines, are only administered once a year.

MS. GREENSPAN: I'm missing something. On the Vitamin D it says, "however, less than half the patient months involve any claims for iron or Vitamin D," and on the page before it says it's 4 percent, Vitamin D. Is that like using a different --

MR. BACHOFER: Hang on. Let me think about that. That may actually be a misstatement, as I was trying to draw the point out of here. I would have to go back and check that, and I will do so. I think the point that I'm trying to aim at here is that these two categories of drugs, particularly in 1B, are very highly concentrated in a small percentage of patients and in 1A they're more generally dispersed across all patients.

Turning to laboratory tests there's a somewhat different pattern that is apparent. Partly, this is the nature, I think, of laboratory testing. Again, looking at the percentage of patients and patient months of claims for

these laboratory tests, virtually 95 percent or more of all patients use anemia labs or Vitamin D labs at some point over the course of a year.

On the infection labs and carnitine, there's a somewhat lower percentage of patients who receive tests related to this. As was pointed out by Bonnie at the outset of this meeting to me on a side bar, that's largely because it's important to keep in mind that the list of tests that are performed here are not performed exclusively for the purpose of dealing with carnitine. They're performed for other reasons as well, but we have no ability to differentiate what was the reason for performing a particular lab test.

But we're looking, again, at more than 75 or 70 percent or so of patients who are actually receiving tests in that category. However, again, consistent with this sort of distinction between the first Bundle 1A being more chronic in their character and being used month after month and Bundle 1B, the percentage of patient months that involve claims for these lab tests in Bundle 1B is only about 20 percent or one out of every five months.

The other labs, as you move to a much longer and

much more expansive lists of services, are again virtually universal in terms of patients receiving one of those at some point in the course of the year, and over 80 percent of months involve those lab tests. So small dollar amounts, again, that are being added on. In the case of Bundle 1A, that small dollar amount is fairly consistent across patient months. In 1B, small dollar amounts, but they tend to be more concentrated in individual months.

If you look at the percentile points on variation for these lab tests, you again see a somewhat different pattern in some way. Claims for anemia tests are being submitted in more than three-quarters of patient months as was seen previously. On average you're seeing $28 and $35 respectively. But in 25 percent for months, claims for anemia tests exceed $40, and then 5 percent they exceed $58. And in Vitamin D tests, a sort of similar pattern, 5 percent a month they exceed $79 per month.

The infection labs and carnitine labs are much more concentrated. They occur in only 5 percent or so of patient months. But, again, the dollar amounts of very small so that in those months in which a claim is submitted, you're seeing about a $35 add on to the total

payment. The other labs are really there for reference, and they show, again, a much more dispersed pattern, so fairly high variability, as you would probably expect, across that large category.

DR. WISH: These are separately billable labs we're talking about, right?

MR. BACHOFER: These are separately billable labs.

DR. WISH: So CBCs that people get to monitor anemia, those are not separately billable, and those don't count, right?

MR. BACHOFER: Those are not shown here.

DR. WISH: So the only ones that would really count would be the iron studies and stuff like that.

MR. BACHOFER: Exactly.

DR. WISH: And you're saying in the previous slide that people are getting those studies 80 percent of the months?

MR. BACHOFER: Yes, that is correct. They involve a claim for one of those tests for iron that is allowable for a median average. Hang on. Let me just sort that out.

CO-CHAIRMAN RUBIN: I'm not justifying it. But what the data shows on Slide 17 is that in any given year, almost 95 percent of patients have an anemia test done, I don't think that's surprising. But in 80 percent of patient months, a separately billable anemia test is done --

DR. WISH: That is surprising.

CO-CHAIRMAN RUBIN: I would agree with that.

CO-CHAIRMAN AUGUSTINE: We required in anemia hematocrit on the claim in order to bill for EPO in a month.

MS. CUELLAR: We are.

CO-CHAIRMAN AUGUSTINE: But if you required to do that monthly, then why would it not be surprising that about 80 percent of months have some type of hematocrit or some type of anemia testing?

MS. CUELLAR: It's not separately billable. The composite is weekly for H&H.

MR. BACHOFER: Subject to a frequency. It becomes billable if it exceeds the frequency.

CO-CHAIRMAN AUGUSTINE: Does anyone here know the answer to that question, what the frequency of hematocrit

in the composite rate is?

SPEAKER: Once a week.

CO-CHAIRMAN AUGUSTINE: It's weekly?

SPEAKER: Is that why, if we go back to Slide 13, that adding the labs in, in 1A add $64 a month?

MR. BACHOFER: Yes.

SPEAKER: It seems to me if we compare Slide 13 with Slide 17, $64 is composed of some sort of sum of very often routine anemia, Vitamin D, and other labs.

MR. BACHOFER: What we don't have in here is we have not attempted to break out the actual frequency of individual lab tests in the anemia category. If you look under Tab C --

SPEAKER: There's a long list of bizarre tests here.

MR. BACHOFER: Right. On page 11 there's a list of the anemia labs.

DR. EGGERS: What's the average cost of an anemia lab? I don't know. What is it?

DR. LAZARUS: That's why hemoglobin electrophoresis is very expensive. Nobody orders that.

DR. TURENNE: If it's helpful, I have some

information on the most common, individual tests in this category. Both in terms of frequency and in terms of dollars that appear to stand out are ferritin assay, iron assay, and iron binding tests.

SPEAKER: Those are iron, not --

CO-CHAIRMAN RUBIN: I think the issue here is that, at least from a clinical perspective, the tests that contribute to the dollar amount that we just heard are ordered in a consistent but infrequent manner

MR. BACHOFER: Right.

CO-CHAIRMAN RUBIN: And I think -- at least among some of the nephrologists around the table -- anemia labs, based on this list on page 11, billed in 80 percent of patient months seems high based on all of our personal experiences. Obviously, the reason we're all on this panel is because we're exemplary nephrologists and not all of the other folks out there, so maybe we're skewing the data and skewing our experiences. But Mike looks at data from thousands of not-as-accomplished nephrologists as he is, and that's not just the way it seems to be going.

MR. BACHOFER: I would also add though one other caution. This includes all lab tests performed both by

independent labs and by the facility. So it may be that there are tests being ordered that are fairly common tests but that are not being ordered through the dialysis facility, so if a patient shows up in an emergency room. If a patient goes to a physician's office, if they have a test performed as a result of a medical event occurring outside the purview of the dialysis facility, it would be showing up in our data.

CO-CHAIRMAN RUBIN: I mean, it still seems like a high number. I guess the good news is that for those people that want to participate in this demo, it's going to drive up the baseline price. And if, in point of fact we all do less, then we can all improve our bottom lines without doing much effort, so why don't we try to get it right.

DR. LAZARUS: But what is the implication, though, of whether these are in and out of the bundle in the future? Does that carry an implication, that all of these tests will be in the bundle?

CO-CHAIRMAN AUGUSTINE: It depends on which bundle we choose.

DR. LAZARUS: Take the simplest, 1A.

CO-CHAIRMAN RUBIN: The implication is that in 1A all of these tests would be in the bundle.

MR. BACHOFER: Right, subject to revision.

CO-CHAIRMAN RUBIN: Data that you presented would assume that all of these tests are in the bundle.

MR. BACHOFER: Right.

DR. LAZARUS: Why in the world would be doing these tests in the dialysis unit? Hemoglobin, G6PD?

MR. BACHOFER: I can't answer that question because --

DR. OWEN: I've got a needle in the person's arm. The patient is seen as a -- by a non-nephrologist --

DR. LAZARUS: But what should be done is what my question is.

DR. OWEN: I'm assuming they're not doing inappropriate tests, so for that patient, for that circumstance, it's appropriate. These guys, as they've told you, are not able to segregate out comorbid conditions and case mix, so you're going to capture all that. All patients are going to look the same.

DR. LAZARUS: My only concern is what's put in a bundle going forward?

DR. OWEN: Which is a different question than what they're answering.

MR. BACHOFER: If there were to be specific tests that you could not plausibly see being included in a bundle, that would be an argument --

CO-CHAIRMAN RUBIN: Well, I think that a lot of this discussion would become much more muted if we had some sense of the frequency distribution. I think Dr. Owen raises a really good point. Sure. If somebody goes to a hematologist, and for some reason, that I can't quite come up with right now, they want to see whether the patient has the G6PD deficiency, it makes imminent sense to take some blood and run the test. If we find out that it's less than X percent of the frequency, then nobody's going to really care.

My sense and what we heard from the Michigan folks was that the big three in this category are exactly what everybody would expect. Assuming you put lab tests in a bundle, those three would be the ones that you'd want to put in. So perhaps we can have it as a to-do list, checking out the frequency distribution. We'll get it out to the committee and we can move on.

DR. EGGERS: The last time we spent quite a bit of time, it seems to me, sort of distinguishing between the lab tests that were billed by the facility and lab tests that were not directly billed by the facility. That distinction seems to be lost here.

MR. BACHOFER: We dropped that for this, yes.

DR. EGGERS: You dropped what?

MR. BACHOFER: We dropped that distinction for this analysis.

DR. EGGERS: Yeah, for this analysis. So what we have in there are those things that the hematologist bills for. The potential problem that I think Mike is saying here is, if we put it into the bundle, then that precludes the hematologist somewhere else for billing for that. And we probably don't want to do that. We want to put things in the bundle that are as closely related to the routine care of the dialysis patient as possible.

CO-CHAIRMAN RUBIN: Well, you don't want to have something in the bundle that you're getting paid for but which you might also have to put out monies for that you can't control. That I think is really critical. If everybody has access to your prescription bed, that's a bad

way to do business.

DR. EGGERS: Right. That was sort of the point I was making.

CO-CHAIRMAN AUGUSTINE: But on the flip side, one of the things we talked about at the last meeting was one of the comments that Dr. Lazarus had made, where people get referred to the facility, and they draw the blood there and perform the tests, and send a console back. Personally, the first program is a major priority for the agency. One of the things we'd like to do is protect these accesses. Personally, I would like it if as many of the blood draws are done in the facility if at all possible because you're going to take care of the access much more than elsewhere.

CO-CHAIRMAN RUBIN: This is an important discussion because where it's done and who pays for it I think are separable issues, and let's put that off till the afternoon. Let's keep going because you're beginning to encroach on --

MR. BACHOFER: Right. We're into the home stretch here. So what do we know now? My sort of summarizing notes. I think that last discussion has been very interesting because we got off on to a discussion

about very specific questions about individual lab tests. What I would go back to is that fundamental slide and say what we're talking about here is $64 to $107. The actual dollar amount that we're talking about focusing on and bundling into this is dominated by the drugs obviously. I think everyone knows that, but it's sometimes useful to be reminded of that and also to revisit the variation and use of injectable drugs, which is showing a very wide dispersion for the big-ticket items, particularly for EPO, and Vitamin D and iron.

So what do we know now? First of all, EPO, iron and Vitamin D dominate the bundle. The expansion of the bundle adds very little to variability within the bundle. It's not like by adding in these additional classes of drugs we suddenly are creating large amounts of variation that we in a sense have to account for. Within that bundle, EPO, iron and Vitamin D appear to be used somewhat routinely, whereas other drugs appear to be used more episodically. It's plausible the different causal chains are driving the use of those two things.

Laboratory tests follow a broadly similar pattern, although it's not as sharply defined. Partly

that's just reflecting the nature of the laboratory test data that we have and partly it reflects the use of laboratory tests I think. Some are used routinely. Others follow a pattern that might be characterized broadly as more episodic. But in both cases the laboratory tests have a limited contribution to both total payments and to overall variation within the bundle. It has significant implications, as we have heard, for administrative issues and for what the responsibilities of the facility are and so on, if they're dealing with services that they don't directly control. In terms of a quantitative picture, a contribution to variation there, contributing relatively low.

This takes us to what do we know about the amount or nature of variation. The variation among patients is raising a fundamental question; to what extent is that variation -- particularly in EPO, iron and Vitamin D, particularly EPO -- clinically justified? Does that variation reflect differences in patient needs or at some level is it reflecting differences in practice patterns? As Bill Owen noted, it raised a question about do administration routes have any impact and so on and so

forth. So there's a series of questions that have to do with what accounts for that variation in the thing that's driving variation; namely EPO, iron and Vitamin D.

The variation in the other drugs raises similar questions, but somewhat different. To what extent should a payment system, for example, try to reflect episodic effects? Do we need to have some kind of an adjustment that the case-mix adjuster should be trying to pick up for things that might in any given month cause variation, significant variation, in use of services in that month, or averaging across months or across patients, is that sufficient to deal with those kinds of questions?

I didn't go into the data on this, but Levocarnitine provides a case in point. It's used by a very small percentage of patients. But in those months in which it is being used for those patients, it is adding about $400 per month to the amount that is being billed. That raises some questions about, well, is that something that should be reflected or in what way should that kind of a variation be reflected.

There's a second set of questions that have to do with variation among facilities. Patient variation is

obviously large; you would expect it to be large probably. But to what extent does patient variation average out at the facility level, to what extent are there systematic differences across types of facilities in the patients that they're treating, and what is the impact of that kind of patient level variation on facilities of different sizes?

Generally, I think people who have looked at prospective payment systems tend to think that differences at the patient level will tend to average out, but we tend to be looking at facilities like a hospital that might have several thousand admissions over the course of a year. These are much smaller facilities if you look at individual facilities with between 50 and 100 patients in them. The issues of laws of large numbers that sort of come in are not as pronounced.

The final question that the variation raises is what kind of risk of patient selection are we running if we simply go into a system that pays a flat dollar amount?

DR. OWEN: I just want to make sure I'm fully understanding what you're saying about the bullet point to subheading 1, "variation may average out at the facility level." So folks who are high users of EPO will all be

high using EPO units?

MR. BACHOFER: No.

DR. OWEN: You'll be high and low.

MR. BACHOFER: You'll be high and low. In other words, you might have a $1,000 range around the median for the individual patient, but when you look at the individual facility, the range of variation on the average patient across facilities will be much smaller than that.

DR. OWEN: Do you guys have data for that?

MR. BACHOFER: We will be showing some of that in the next presentation.

DR. OWEN: All right, excellent.

CO-CHAIRMAN RUBIN: Hopefully, it will still be the morning when we do that.

(Laughter)

MR. BACHOFER: Moving right along, unit of payment. Just very briefly, sessions do effectively appear to determine monthly payment of the composite rate and sort of automatically adjust for events that occur during the month for composite rate services. Separately billable items are more weekly related; different events have different effects. As we see in some of the discussion in

the next segment of this, there's probably going to need to be some kind of an adjustment for those events. There's no obvious solution. Either per session or per month payment will probably require some kind of an adjustment.

This is basically the final slide here on what are the policy considerations, and that's essentially the gist of the discussion I think for this afternoon.

CO-CHAIRMAN RUBIN: Great. Thank you very much. We appreciate it. I think this was a useful discussion that raised a lot of issues for further discussion this afternoon.

The next presentation is going to be preliminary case-mix analyses. I'd like to ask Dr. Wolfe from the University of Michigan to introduce the people he brought with him, as well as whoever is going to be making the presentation.

DR. WOLFE: Thank you. I'd like to introduce Richard Hirth, an economist; Jack Wheeler, also at the University of Michigan. Joe Messana is a clinician. He has helped us with a lot of clinical input that's been very useful in understanding some of the issues here. Mark Turenne is an economist working with us as well.

We're going to split up the presentation. Jack's going to start out and Richard's going to finish up with some of the specifics of some of the analyses, and I'm recovering from jet lag.

DR. WHEELER: Thank you. The next section on preliminary case-mix analyses is meant to advance several objectives that Henry led us into. One is to inform your deliberations regarding what should be in the bundle, what are the components of the bundle; your deliberations about the unit of payment; and your deliberations about other kinds of design conditions.

The second principal objective is to describe the potential for case-mix analysis that is inherent in the data that we have in the general sense. The highlight of this particular slide is on preliminary. That's because in order to develop a final case-mix model, several preliminary questions have to be answered. Since I'm a chicken farmer or rancher, I will say that this is kind of a chicken and egg set of circumstances. In order to determine the case-mix adjustment, we have to know what's in the bundle. But we're going to be presenting to you a lot of information about preliminary case-mix analyses so

that you can sort of assess what should be in the bundle.

That's the first prerequisite question. The second is, how frequently and at what dose should each service in the bundle be reimbursed? This is essentially an issue of whether we should be using historical data, as we've discussed a little bit earlier, or should we be using some kind of normative specification of appropriate care in determination of the bundle and case mix. Then finally, what is the appropriate unit of payment? Should it be month, should it be per session, or some other determination.

The establishment of a case-mix model and case-mix payment system also requires some sort of multiple, preliminary decisions. The first really is how should utilization be measured. That once again goes to should we be using historical -- Medicare allowable -- charges or payments or should be looking at actual counts of units of service, EPO dose, et cetera.

Second is how should the payments be adjusted. Some of the choices that are available to us in terms of the data that we have on hand are using baseline patient characteristics that describe the characteristics of the

patient at the onset of renal replacement therapy; case-mix measures that we get from patient billing data and that can be updated over time; information on prior utilization of the patient that we supposed could be subject to more gaming than some of these others; and then perhaps some other sort of adjustment opportunities that we'll describe as our presentation progresses.

A key question is whether the system should be based on separate models for each component of a bundle or should we have an aggregated sort of case-mix adjustment model. The question here is, do we kind of lump all Medicare allowable charges that are defined by a bundle into -- let's call it a depended variable, and do case-mix analyses on that total allowable charges number? Or would we have separate models to describe the composite rate, EPO, the labs, et cetera. That's kind of a key case-mix analysis question we'll be talking about a little bit later.

Another one is, should there be separate adjustments for each dialysis modality? Should we have a separate case-mix model for hemo versus PD patients or should there be one case-mix adjustment model? Those are

just some design issues that would be required for CMS to be looking into.

Before we get into presenting some of the results, we'll be kind of thinking down the road of some host implementation issues that we're going to come back to at the end of our presentation.

Bundling and case-mix adjustment imply incentives that may change behavior and how the system is put together in bundling may have implications for the data availability of a system going forward. In terms of the incentives, the first point up there is what issues are likely to arise upon implementation that have to do with potential substitutability or substitution of services that are in the bundle; that are services that are out of the bundle for services that are in the bundle, and/or what potential is there for substitution of services by non-dialysis providers, providers that are outside of the deal, for those that are inside the deal.

In terms of data collection, we've already had a bit of discussion about that. We may want to collect specific information for a more complete case-mix adjustment, other than what we can get on the patient bills

and other data sources that we have available. We have had discussion on these final two points, which is how should the payment system be updated or how can it be updated without itemized billing data and how can quality be assured similarly without itemized billing data; do we have to retrofit data on encounter information in order to be able to accomplish these objectives

The specific objectives that our preliminary analyses are meant to fill are first to explore the face validity of the data that we have available for purposes of developing a case-mix adjustment. What do the data allow us to do in terms of understanding variation?

Second, to kind of continue Henry's presentation on the variation in payments, starting with variation in unadjusted payments which he's already well-described, and then going to describing the variation that occurs across facilities and across patients within facilities, and finally even within patients but across months. We have some information that may help us understand some of this variation.

Really, principally, our objective in the next set of tables is to inform your deliberations on the

selection of what are the components in the bundle, what might be the unit of payment, should the modalities be treated differently in terms of case-mix adjustment and payment, and then what specific case-mix measures should be in the final model.

The work to be done after this meeting is to do some analyses that help us to determine whether we need to do some trimming of the data, what patients and values, kind of our outside reasonable levels that should be trimmed; to develop the specific case-mix adjustment factors, and that really presupposes some significant amount of work on refining the list of case-mix adjustment factors and making it shorter; to evaluate methods for controlling for variation that might not be due to case mix; that is might be due to facility characteristics and might be due to other measures of patient need that aren't, at least at this point, captured by our data; then to develop some final case-mix proposals for your consideration to conduct subsequent to that impact analyses of the case-mix bundles for both providers and patients; and to address the question that has already arisen this morning, which is what are the payment options for

outliers.

Just to review, the payment data that we have had available to us are the Medicare allowable charge data. We focused our analyses on separately billable services not including the composite rate, and, specifically, analyses on example Bundles 1A and 1C that we've been discussing this morning.

The data principally come from CMS paid claims for the year 2003, and you can see that they include the dialysis facility claims and claims from other providers.

MS. GREENSPAN: One question I have is if we're concerned about the possibility of people using substitutes after the implementation of a program, what do we know about the use of substitutes now? Do you feel that the payment data that's there is comprehensive enough to give us information? If people are going to go outside to substitutes, are we capturing those substitutes?

DR. WHEELER: The determination of whether there's going to be substitution or not depends largely just on how tightly we define what's in the bundle. If we specify the bundle in terms of specific codes, the opportunity for substitutability is expanded. If we define

the bundle in terms of a wider range of definitions, or wider range of codes let's say, then the opportunities for substitution are diminished.

I'm not sure exactly how to answer your question other than that since we haven't set up --

CO-CHAIRMAN AUGUSTINE: Since they're primarily analyzing fee for service -- things are billed on the fee for service that there's not really a substitutability issue. For example, if we do an expanded bundle that includes Epogen but doesn't include blood components, then you could see an incentive for people to all of a sudden stop providing EPO, transfuse people. And not only do you reduce your cost and increase your margin in the bundle, but you also can bill a separate billable items. It's things like that we need to be aware of, and that's what he's talking about when he means substitutability.

MS. GREENSPAN: Right. But I mean even in separate providers, that would bill separately from a separate provider, and they wouldn't necessarily receive those services anymore with us. Are people already doing that now? Are people already using separate providers that we're not capturing for services that we're going to be

including in the bundle?

DR. EGGERS: I think those are the providers they can bill.

DR. WOLFE: Right. We have all the providers and everything that they bill for is going to have some code, so we're going to capture it in that sense.

MS. GREENSPAN: Okay.

CO-CHAIRMAN RUBIN: Why don't we keep going?

DR. WHEELER: At this point we have kind of cast a very wide net in terms of potential case-mix adjustment measures that could be included in a system. This is our list. It includes the demographic characteristics of the patient, how long the patient has been on renal replacement therapy, measures of body size, lab values, some measures of functional status that we have available to us and help behaviors. We have in the models 36 comorbidity conditions that we've been using and whether there was a hospitalization in the prior month. In some of the analyses we have specification of the type of month; that is whether the month included hospitalization for the patient, whether the patient died, to capture the extent to which we're looking at months that are principally

interrupted course of therapy versus the uninterrupted. And in some subsequent analyses and some exploratory analyses that we'll present right at the end of this hour, the prior EPO dose response that Tom had brought up as an interest a bit earlier.

CO-CHAIRMAN AUGUSTINE: You get EPO and adequacy on the monthly claims, correct? That wasn't included on this list. It says laboratory value, hematocrit at the start of renal replacement therapy, which I would take would be the 27/28.

DR. WHEELER: Yes, that's right.

CO-CHAIRMAN AUGUSTINE: But we also get it on a monthly claim as well, so we need to incorporate that.

DR. HIRTH: Well, it's an outcome of therapy, so it's not clear that you want to incorporate it in a case-mix adjustment model.

DR. WOLFE: But that's in the prior EPO use measure. We'll talk about that towards the end.

DR. WHEELER: The comorbidity measures that we've been looking at have been identified using two principal data sources, the medical evidence form at the start of therapy and the diagnoses we can pull off of the claims.

The claims are, as you can see, inpatient, outpatient, and all kinds of physician claims for Medicare beneficiaries.

The current measures of comorbidities are based only on claims as opposed to the medical evidence form. The data on the claims were more predictive of MAC payments for separately billable services than were the measures on the medical evidence form. We often had a choice of which source to use and the claims data were more predictive, generally.

The specification of relevant claims for determination of comorbidities or diagnoses depends on the type of condition. We used a longer time window for chronic conditions and a shorter time window for acute conditions in terms of what we've done so far.

DR. WOLFE: Jack, I just wanted to amplify one thing. This is not to suggest that this is where the data would come from during implementation; these are the data that we have available now. There would very likely be changes in the way data are reported after implementation.

MS. RAY: Just one question. The current measures are based on claims. You looked at the ICD9 codes and you used the most frequently ones reported? Can you

give me more specificity as to what was done there?

DR. TURENNE: We looked for specific diagnoses that were linked to a certain comorbidity, and any appearance of those diagnostic codes, the ICD9 codes, were used to indicate whether the comorbidity was present. For example, within six months if there wasn't any diagnostic code that indicated an infection, we considered that patient to have had some kind of infection within the last six months. It's broad in that sense for that category, for that comorbidity. But for each comorbidity there were a list of ICD9 codes. We looked in the claims, and one of those diagnostic codes would then indicate that that comorbidity was present over the relative time period.

DR. EGGERS: Well, I will second-guess you on this. In terms of the difference between Part A and Part B billing, the feeling is that a lot of Part B billing could be rule-out code; somebody comes because you suspect they might be sick and so you put that down, and you don't know whether that was actually validated. Typically, I think the researchers look for -- if it's a Part B claim, at least a couple of them separate it by some amount of time before you label that because I think you'd get an

over-identification otherwise.

DR. HIRTH: We didn't use any ICD9 codes that appeared on lab claims for that reason.

DR. EGGERS: Even on a physician office that would be a little bit suspect.

DR. HIRTH: Thank you.

CO-CHAIRMAN RUBIN: Okay, Jack.

DR. WHEELER: In terms of the basic modeling, we used multiple regression that is intended to explain variation in Medicare allowable charges using available case-mix measures. The dependent variable in the analyses was the log of payments per session or payments per month. We used the log transformation because it just was a better fit. Statistically it's equally easy to use a linear specification, so we've done that as well. We converted the log results into a dollar scale for interpretability and that gives us kind of an approximation of the standard deviation that we can talk about in terms of our results.

Please note that the conversion to a dollar scale doesn't account for budget neutrality. So what we're really talking about here in terms of dollar values is relative explanatory amounts rather than sort of absolutely

dollars. It's going to be close, but it doesn't account for any kind of scaling for budget neutrality.

Right toward the end of our presentation we'll present some additional analyses that are intended to distinguish -- what we'll see is that the case-mix measures explain some of the variation in Medicare allowable charges, but the subsequent analyses are then there to help us understand what of the unexplained variation is kind of associated with facilities, patients and months or how we can distinguish the unexplained variation in terms of facilities patients and patient months. Subsequent analysis is based on a 2 percent random sample of facilities. That subsequent analysis is highly resource and time intensive, so it's not based on the universe but rather on some samples that we have drawn and it's very exploratory.

The last slide before we get into some of our results is the unit of analysis, as we've been talking about this morning, is the patient month because those are the data that we have available and that's converted into payments per session or payments per month for purposes of our modeling.

We started with an aggregated model for separately billable services for the two bundles that we're going to present versus a disaggregated model. The aggregated model in terms of regression specification has the following form, where Y is the dependent variable, which is Medical allowable charges, and that's attempted to be explained by the patient characteristics, which are the X values here. The beta coefficients are indications of the strength of the relationship between a patient characteristic and the total Medicare allowable charges.

This particular model is kind of distinguished from a disaggregated model, where we would actually take different components of the bundle, look at EPO, look at other injectables, look at labs, and come up with the relationship between patient characteristics and spending or charges for those disaggregated components.

CO-CHAIRMAN AUGUSTINE: So basically do a case mix on each component as opposed to a case mix on everything together?

DR. WHEELER: You certainly could do a case mix on each component as opposed to a case mix on the whole thing. Please note that this one is an aggregated model of

separately billables only; it does not include the composite rate.

Let me turn it over to Richard.

DR. HIRTH: We're going to be presenting a variety of analyses of different case-mix models, and each pair of them in many cases has a particular purpose that it's trying to accomplish. We're going to be looking at analyses that will relate to verifying face validity in the data, looking at the effect of high payment months, issues such as what happens to the ability to case-mix adjust when you broaden the scope of the bundle, unit of payment, modality, HD or PD, and using various other types of risk adjusters beyond the basic patient demographic and comorbidity conditions.

This table attempts to kind of summarize all the models we're going to be talking about. To interpret the table the easiest thing to do is to consider a base model. Our base model is one that does payments per session rather than per month; that doesn't adjust for the type of month, in other words, hospitalization, transplant, death and so on; that doesn't adjust for the measure of prior EPO dose response that I'll talk about when we get to that

particular model; that uses HD patients only and uses, in fact, all of the data, all 1.94 million patient months.

The cells in yellow indicate a model that deviates in one or more ways from that base set of assumptions that I described. For example, Model 5 uses log payments per month instead of per session. You'll see highlighted in yellow the models that vary those base assumptions.

The first thing I want to take you through before we talk about any models is just a description of EPO payments by month. The range is down in the bottom. For example, the 2 indicates no EPO up through 2,000 units per session. The 4 indicates 2,001 units through 4,000. So the number indicates the upper end of the range that each bar represent.

What I want to point out to you here or focus your attention on are the high EPO months. We've highlighted in the left bar chart that about 1 out of 8 patient months involves greater than 12,000 units of EPO per session. That's a relatively small amount of patient months, but it shouldn't be terribly surprising. It accounts for a pretty significant fraction of spending. If

you look on the right graph, the yellow bars indicate that distribution by dollars. In fact, those 12.8 percent of months with more than 12,000 units of EPO per session are going to account for nearly 40 percent of the spending on EPO. The take home from this is just that in terms of a case-mix adjustment, it's a relatively small number of months that are expensive, but it's not a relatively small number of dollars. Even if you look at that catch-all category of greater than 30, it's about 1 percent of months, but it's about 7 percent of spending in those months, so there are certainly months that we need to worry about.

Here's a little bit more descriptive data before we get into the models. This block just indicates at what level does the variability in the raw data occur. If we look at the box and whiskers on the left that's labeled "patient month," that essentially says that if we look at kind of the broad range there, the 5th percentile to the 95th percentile, you've got a range of about $25 to $250 per session. That's the variability between the patient month at the 5th percentile and the patient month at the 95th percentile.

Some of that variability kind of washes out at the patient level. It's that left box and whiskers that indicates all the variability in the data. It could be that one patient is different than another patient consistently; that within a patient some months are more expensive than other months, and that some facilities are more expensive than other facilities. All of those sources of variation will contribute to that big range in the left box.

If you look at the center one, we've taken out the variability across months within a patient. If we look at the Medicare allowable charges per session at the level of all the sessions that were delivered to the patient during the calendar year 2003, you see that it's a little bit of a narrower variation. We're no longer going from 25 to 250, but still pretty substantial, going from maybe about $35 at the 5th percentile up to maybe about $230 at the 95th.

The final box indicates how much variability there is at the facility level. If we aggregate all the patient months that are treated at a given facility over the year 2003, we see there the range is about from $60 at

the 5th percentile to maybe about $130, $140 at the 95th percentile. That just indicates the levels at which some of this variation is occurring.

Now we're going to kind of jump into the models. What I like to do with the models is to, given that we're getting close to lunch, just kind of take you through what's a lot of numbers and try to draw out some of the main take-home messages.

Model 1 that we described in that grid is the model that we use primarily to assess face validity of the results, are we getting clinically plausible outcomes. What we do there is focus not on one of the bundles per se, but just payments for EPO and iron. If we think of it as drugs used in anemia management, that has a much cleaner clinical interpretation than separately billables. Separately billables are for all kinds of stuff, so it might be a little bit harder to say whether you'd expect a particular relationship to exist in the data or not.

Since we have 1.9 million months, everything's statistically significant even if it's not practically important, so I want to highlight those things that have a practice level of importance. We kind of arbitrarily

define that as indicating a 10 percent or more differential and separately billable cost per session.

The characteristics such as the early months of renal replacement therapy, which are clearly the first six months, indicate spending at greater than 10 percent above the baseline level. Women have higher spending. We actually put in an interaction term of females 18 to 44 have particularly higher spending on anemia therapy. Larger patients had higher spending. Those with lower baseline hematocrit had higher spending. The comorbidities that had the biggest effects are infections, several bleeding conditions, anemias and hematologic cancers, and then months following hospitalization. If you were hospitalized the month before, you tended to have more than 10 percent elevation in your EPO spending per session in the subsequent month.

I'm going to highlight a few of the things that had relatively smaller effects that didn't make our 10 percent cut. Age didn't make the 10 percent cut. Race ethnicity. With the exception of a very small group of Pacific Islanders, all the race ethnicity effects were less than 10 percent in magnitude; most of the measures of

functional status, things like medical evidence for measurability to transfer or ambulate. Health behavior measures such as drug dependence and smoking didn't have effects that exceeded 10 percent in absolute magnitude.

One thing we would like to get your feedback on either over the break or in the afternoon is sort of your reactions to the things that were or were not significant in terms of magnitude here. The one interaction term we had between female in the age 18 to 44 group, that was important. We haven't done a lot of other interactions in particular. If there are other factors that we can look at in an interactive way that might be important, that would be certainly quite useful to us going forward.

This is the first of a number of slides. It's going to have the same basic structure. I'll kind of take you through some of the highlights of this slide, then we can go more quickly through some of the others.

This is essentially what I call the null model. This is just the raw, unadjusted data, so there's no case-mix adjustment here at all. We've got nearly 2 million patient months that focuses on Bundle 1C and uses payment per session as the dependent variable for HD

patients.

If you look at the average payment for the things in Bundle 1C, it's a little bit over $100 a month. The R^2 is obviously zero because we have no model here. The unexplained variability, since we have no model, all other variability is obviously unexplained and is about $81 a month. What that says is under the current fee-for-service payment system, the typical patient is paid $101 per session and that varies patient to patient with a standard deviation of $81. That's the current payment system, $101 on average up or down, $81 for standard deviation.

If we look at the bottom panel, those numbers indicate sort of where that unexplained variation is coming from. We see that part of it is coming from the facility level. Note that these things don't add up, so don't try to add the three numbers on the bottom and get the $81. They add up when you square them and do it on the log scale. I don't want to have to take you through that. Just trust me that they add up in that way and they don't add up in terms of the numbers here.

The variability at the facility levels of standard deviation are plus or minus $16. At the patient

level, for patient to patient, it's about $48. If we look within patients, the month-to-month variability is about $40 per session.

DR. LAZARUS: This includes 13 treatments?

DR. HIRTH: This is payments per session, so it's standardized by the number of sessions any patient month. If you have only one treatment, then there will be just --

DR. LAZARUS: I'm looking at the variation of the patient and it's $81. So there are people out there that get $20 per dialysis?

DR. HIRTH: Separately billables, the separately billables in Bundle 1C.

DR. WOLFE: And be careful with this because we translated this back to the dollar scale. Just to make it easy to think of a plus or minus, it's really multiplicative, so it's more like a 2 to 1 factor. It goes from 100 down to 50 and up to 200. But it's easier for people to do plus or minus. But don't worry about that lower end when you subtract if it gets close to zero. That's just because it's really on a multiplicative scale instead of an additive scale. This is just to give you some idea of the magnitude, but don't worry about whether

it makes perfect sense. It gives you the relative magnitudes of these components of variation.

DR. HIRTH: So now we're going to jump over to our first model, other than the face validity model, the first model of a bundle, which is going to be Model 3 in the grid. On the left I've just repeated what was in the last slide, what's the raw variability when there's no case-mix adjustment. Model 3 is what we call kind of our basic model and includes all the case-mix measures. It doesn't include sort of the extras like EPO dose response or type of month. So, again, you've got the $101 average payment. How much of the variation around that $101 is explained by these basic demographic and comorbidity measures. It's about 7.5 percent.

If you were to base a case-mix adjusted payment for Bundle 1C on this model, the predicted variation of $22 indicates that your typical payment as a standard deviation above the mean level of payment would be about $22 more than the $101 mean, and of a typical patient who was 1 standard deviation less expensive in terms of the prediction of the model would have a payment of about $22 less.

If you compare that to the null model, which would just pay the flat $101 for the bundle to everybody, you get obviously substantially more variability in payment than you would by not case-mix adjusting, but substantially less variability in payment obviously than the current fee-for-service system which is the plus or minus $81.

One thing that I want to draw your attention to is the correlation of prediction errors. What I mean by the correlation of prediction errors is we take a model, and let's say the model predicts that you're going to cost $150 a session. So it predicts you're going to be about $50 more expensive than the average patient. Suppose, though, this month you actually cost $200? Essentially the model under-predicted your real cost by 50 bucks. It said you'd be about $50 more expensive than average, but in reality you are about $100 more expensive.

Ideally we would hope that that prediction error would kind of wash out from month to month. If you are a model under-predicted how expensive you were this month, it's because you had a bad month. If you go out a few months, you're going to be around that $150 that the model thinks you are going to cost.

The reality is it's not quite that easy. If we look at the correlation of the prediction error, from one month to the next it's about .7. So it's a relatively high correlation. The patient that the model says is going to be $150 but actually cost $200 is going to tend to still be more expensive than the model predicts next month. Even at going 11 months ahead the correlation is nearly .4.

What that says is if the model under-predicts how expensive you are this month, you're going to tend to be more expensive than the model predicts going forward as well. The flip side of course is if you're actually cheaper than what the model says, you're going to tend to be cheaper than the model says on into the future as well. That's certainly something I think we ought to discuss in the afternoon.

MR. CANTOR: On the R^2, the correlation coefficient, I thought that was supposed to be from 0 to 1. Why is there a percentage here? What does that mean?

DR. HIRTH: 0 to 1 would be from 0 percent to 100 percent. It's just reporting it in percentages. You could think of 1 as being 100 percent.

MR. CANTOR: So this is really 7 percent.

DR. HIRTH: It explains the less than 10 percent of the variation. In that sense it is really poor. Most case-mix adjustment models don't explain an awful lot of the variation. It depends on what your standard is. If the standard is explaining everything, it's lousy. If the standard is explaining what typically can be explained, it's not that bad.

DR. EGGERS: I'm probably wrong about this, but I think Joseph Newhouse published an article maybe 20 years ago on the maximum predictive amount for individual variation in health care, and it was somewhere -- theoretically I don't know how he did it, but like 25 or 30 percent was the maximum theoretical amount he would predict.

DR. HIRTH: There are always going to be random things that happen. Somebody's going to be hit by a bus and you're not going to be able to predict that.

CO-CHAIRMAN RUBIN: He has done some more recent work.

SPEAKER: In '96.

MR. BACHOFER: If I could just add to this on a point of clarification. These models here are individual

patient-level models, which it is notoriously difficult to predict at the individual patient level.

DR. HIRTH: That's why it says patient month level.

CO-CHAIRMAN RUBIN: Dr. Owen?

DR. OWEN: I was just going to say, if you get double digits with ESRD patients, you're doing great. This ain't bad.

CO-CHAIRMAN RUBIN: Okay. Dr. Wolfe?

DR. WOLFE: Richard, were you going to go over the bottom three numbers as well? I had a couple of things to say about those three numbers.

CO-CHAIRMAN RUBIN: Before we get to those numbers could you do --

CO-CHAIRMAN AUGUSTINE: I just want to say 10, 15, 25 percent is ideal. I mean, it's all relative. If we're in an experimental setting, then of course we're shooting for 80, 85, 90 percent. But this is observational data with a myriad of factors that we absolutely have no idea about. I think we're not doing too bad.

DR. WOLFE: Just some exercises, mental exercises. If you had 100 percent explanatory power, that

would mean that physicians were doing exactly the right thing. There would be no reason to bundle whatsoever; just let them go ahead and do exactly the right thing, and pay them for it. The fact that there is something else going on beyond what we can predict suggests maybe some of it is due to our lack of ability to predict it, or maybe it's due to physician discretion, which probably doesn't belong in the payment system.

I do want to mention about the bottom three numbers. Richard just said we've explained $22 plus or minus, above and below $101; unexplained is $77 or $78. Down at the bottom we break that into how much of that is differences between facilities. About $16 remains due to facility characteristics of some sort. That can be efficiency; that can be different practice patterns. They may just do things differently. Some facilities may choose to provide more separately billable services than others on average regardless of the type of patient they have. We can't distinguish between efficiency versus just practice pattern right here, but it's about plus or minus $16.

The patient-to-patient variation comes in at about $40, plus or minus $40. When you look at the type of

patient they are, some patients cost 40 bucks more, some patients cost 40 bucks less. An easy calculation to do is what happens at the facility level with that amount of patient-to-patient variation.

If you had a facility of 25 patients, you take the square root of that; that's 5, and you divide that standard deviation by 5. So at the facility level that amount of patient variation would lead to good luck or bad luck and whether you had a difficult case mix or an easy case mix at plus or minus $8, because you take that plus or minus 40 and you divide it by the square root of the number of patients.

If you have 100 patients, just by bad luck or good luck you can have a heavy case mix or an easy case mix of about plus or minus $4, depending upon the size of the facility. So the bigger the facility, the less risk there is that your case mix is going to adversely or beneficially affect you. The smaller it is, the more adverse or beneficial effect the case mix can have. It goes down pretty rapidly with the size of the facility. The month-to-month variation washes out pretty quickly because you've got 12 months. And that is really just from month

to month some months the patient is high and some months the patient is low.

Really what I think all of us are concerned about is this $42 at the patient level, plus or minus that's unexplained. But when it is averaged at the facility level, a lot of that does go away. Sorry for the interruption, Richard.

DR. BURKART: Just to be clear on that, you're saying it's $42 plus or minus what the model predicted. So for the average it's $101, but for Patient A it might have predicted $150, and then the variability is 42 plus or minus the 150, not the 101.

DR. WOLFE: Perhaps, but let me repeat it. It's 101 on average, but the model says it's 101 plus 22 for some patients and minus 22 for some patients. That's what we can predict based upon the characteristics. In addition, the actual payments unfortunately weren't exactly whatever we predicted. They varied above and below that by about plus or minus $40 from patient to patient, unexplained. So the bottom part is unexplained variation, some of which is due to facility practice possibly and some of which is due to patient characteristics.

MR. BACHOFER: The $15 that you show there for facility, unexplained variation might also include omitted case mix or unmeasured case-mix variation?

DR. WOLFE: Undoubtedly, although, again, because of the averaging effect, it's probably more due to practice patterns or efficiency.

MR. BACHOFER: I just didn't want to go down the path of all facility variations.

CO-CHAIRMAN RUBIN: Just to remind you, we're about out of time. What we're going to do is give you additional time, but we're going to take that away from lunch.

DR. HIRTH: So I'm the one that's getting beat up. I'm going to take you briefly back to the anemia management model, the EPO and iron model because, again, this is a little bit of a face validity issue, taking a look at outlier.

What we did is just randomly decided to trim out the top 1 percent of spending per month. So we took the 1 percent of months that were the most expensive in dollars per session, kind of just arbitrarily defined that as sort of an outlier payment level and said how well does a

case-mix model do at explaining the other 99 percent that we didn't trim out as compared to when you use the 100 percent of the data and what happens to the variability.

Essentially, the trim level is at about $320 per session of spending, so it's a pretty high spending. So if three-quarters of it is EPO, that would be about 24,000 units a session, so it's about five times the median level. It brings the average payment down by nearly $4, from about $73 down to $69. The R^2 tells us when we use all the data, we're not quite as good at explaining EPO and iron spending as we do when we trim out a high 1 percent, and high 1 percent is a little bit harder to explain than the average patient month.

If we look at the predicted variation, it goes down by about a dollar. That's probably not surprising, though, because there's less variation to explain the average payment has come down $3. The unexplained variation, by trimming out that highest 1 percent, goes down by $13, so by trimming out that highest 1 percent there's obviously going to be less of a tail out there.

In the interest of time, let's move quickly to

scope of bundle. This compares Models 2 and 3. What we do here is we say, what happens if we broaden the bundle out? Is it harder to predict spending for a broader bundle than it is for a more narrowly-defined bundle? In other words, is there more risk from broadening the bundle to facilities?

The average payment goes up by about $8 a month, so we talk about 1A versus 1C. 1C brings in about $8 per session of additional separately billables that were not included in Bundle 1A. The overall explanatory power is actually a little bit better. We do a little better explaining as a proportion of variation the broader bundle than we do the narrower bundle. So there's no evidence that broadening the bundle out from 1A to 1C deteriorates the ability to explain variations in spending in that bundle.

The predicted variation is the $22 we saw before in Bundle 1C. It's a little under $20 in the smaller Bundle 1A. So part of that decrease in predicted variation is because the R^2 is lower and part of it is because the average is lower; there's less variation to predict. I think I'll just leave it at that for this one and move on

to unit of payment.

DR. EGGERS: You were showing us the expanded bundle before, and this one shows the unexpanded bundle. So you started with the expanded and went back to this.

DR. HIRTH: Right. The right column is the model I showed you before, the $22 predicted variation; exactly.

If we look at unit of payment, whether it be a per session model or per month model, the per session model, the one that we've been talking about as our base with $101 average payment and R^2 of about 7.4 percent, you have better ability to predict payments at the per session than the per month level. The R^2 at the per month level is only about 4.5 percent. Largely that's because the per month model does not control for the number of sessions in the month. We control for the number of sessions basically to generate back into the per session model.

If we take the per month model and we add in indicators of the type of month -- were you hospitalized, did you die, did you receive a transplant, did you start dialysis -- since a lot of those types of months are strongly related to the number of sessions, then the per month model comes a little bit closer to the R^2 or the per

session model, but it still falls short. It's about 5.5 or 6 percent when you add the type of month.

We see some very big discrepancies between an HD model and a PD model. The first discrepancy, going back to the descriptive data we presented at the first Advisory Board meeting, is that the average payment is much lower for PD, $40 versus $100. Not only is the average payment lower; our ability to explain variation around that average is much lower. We essentially explain none of the variation of PD payments, .3 percent R^2. If you look at the magnitude of the variation in payments that will result from a case-mix adjustment system based on the models, as opposed to the $22 plus or minus we predicted for HD, it's only about $5 plus or minus for PD.

The other interesting thing about PD is we don't get nearly the consistently from month to month in the prediction error. Maybe that's simply because we're not predicting much. The prediction error, though, should still kind capture if you're not predicting well. We had the .7 correlation from one month to the next, in HD .4 correlation 11 months out. For PD there's only about a .2 correlation for a one month prediction error. So if you

are more expensive than predicted in one month, there's a pretty low correlation with being, again, more expensive than predicted the next month. If you go 11 months out, it's essentially uncorrelated.

DR. EGGERS: Does a PD session have a meaning?

DR. WOLFE: Thrice weekly. It's translated to thrice weekly. It's a three-week equivalent session.

DR. HIRTH: So a week of PD is considered to be equivalent to three hemodialysis treatments.

DR. EGGERS: So Medicare is paying only 40 percent for PD what it pays for --

DR. HIRTH: Separately billable.

DR. EGGERS: Sorry.

DR. HIRTH: The iron and Vitamin D, a lot of it will be oral.

DR. LAZARUS: That's because of the ability to give those two products to the PD patient, I would think.

CO-CHAIRMAN AUGUSTINE: Also, the previous month correlation. From my understanding in talking to a lot of PD patients, they don't come to the doctor's office or facility every month. They'll come every few months, and at that time they'll be prescribed EPO to take home.

That's one reason why that may not show up to be so significant.

DR. HIRTH: Right. There are a lot of months that are zeros. We actually printed out a lot of the data and just looked at the pattern by month for PD patients. There are a lot of months that have no separately billables. Some patients will have them every month. But among the ones that have some zeros, like a constant quarterly, there's not a solid pattern where you can say, aha, they're going in every quarter and they're getting their EPO that month. It's a lot more random in terms of what months are zeros.

We're going to talk a little bit before we conclude about some of the other types of risk adjusters, things that go beyond the patient demographics and comorbidities.

The first is what happens when you add the type of months. An indicator for essentially the base would be sort of the full number of sessions that were expected with no indicator of an event like being hospitalized, dying, getting a transplant, switching modality, starting dialysis. When we add indicators for the type of month, we

are able to increase the R^2 by nearly a percent, to a little over 8 percent. In terms of the predicted variation, it goes up by a little more than a dollar. So by adding the type of month, you can do a little bit better in terms of predicting, spending, but really not dramatically better. You're not quite as much of an improvement as if you would have asked me what I expected before we ran the model.

The final type of predictor that I want to talk about is kind of a prior EPO dose measure. We averaged the EPO use in April through June 2002, so it's six to eight months prior to the beginning of the year, where we're now trying to predict costs. It's a historical measure. We average the EPO dose in those three months and divide it by the hematocrit achieved in those three months.

It turns out that's very collinear just using the EPO dose because the EPO dose goes like this from month to month and the hematocrit goes like this from month to month. Essentially, the average of the ratio of EPO to hematocrit is really pretty close to being the EPO dosage and what that was in this period from April to June 2002. We're looking at essentially an EPO dose that occurred six to eight months prior to the beginning of the year; we're

trying to predict costs.

That effect over-doubles the R^2 of the model, so from 7.5 percent over 15 percent. In other words, if you needed a lot of EPO April to June 2002, that's still going to predict that you're a much more expensive patient in calendar year 2003. If we look at the predicted variation, we go up by nearly $10, from about $22 plus or minus the standard deviation to about $32 standard deviation plus or minus.

The correlation of prediction errors goes down a little bit. It's a little less severe than it is in the basic model that we talked about, but it doesn't go down dramatically. So, again, something is a little bit surprising to us. I'm not going to try to argue. This is the best way of measuring prior EPO utilization. It's just a quick and dirty way that we calculate it just to kind of give you some descriptive sense of what the explanatory power of such a measure might be. There might be a better way of measuring it, and certainly there's a question of whether that's something that should be adjusted for. But if you want to explain a lot more of the variation, looking at some of these prior utilization measures, as you can see

from the R^2, is kind of the obvious path to go down if your objective is to maximize R^2.

CO-CHAIRMAN AUGUSTINE: I want to ask a question of the clinicians here. There's been a lot of papers written about people at the bottom are kind of sticky and stay down there. What does this mean from a clinical perspective in the sense that the very high cost patients, if the bundle maybe puts an incentive to do more transfusions as opposed to just pushing more EPO, how would that impact on decision-making?

DR. LAZARUS: Well, if you left here, Brady, and got in an accident and bled down to a hematocrit of 20, I hope the doctor that sees you is going to give you a blood transfusion and not EPO. There are some people that ought to get transfused. If they don't respond to the drug, you ought to transfuse them. We've got hysterical in this country about not giving blood transfusions. There are some people who ought to get blood transfusions. I would hope if we do what's proper in a bundle it's not deemed as being something inappropriate. That's my view.

There are just people that use massive doses of EPO. I ask physicians all the time, why don't you

transfuse the patient if you're worried about their cardiovascular state?

CO-CHAIRMAN AUGUSTINE: In an expanded bundle environment, if that type of reasoning happens, that would be one of the behavioral offsets. It may not prior utilization predictive of future utilization because people may not be as sticky if transfusions are used more than they are today. Is that a safe statement to make?

CO-CHAIRMAN RUBIN: No. I don't think anybody really knows the answer to that because you can use less or more, depending on what you think the right hematocrit number is. I think that, again, this is one of those issues that you can get at in a couple of different ways; the cost for an extra 10th of a gram of hemoglobin and you put that in a P4P measure. I mean, there are all kinds of creative ways that you can deal with that, and make sure that people get transfusions by picking some hemoglobin number that if you fall below, you get a bad mark and if you're above you get a good mark.

DR. WISH: I was just going to respond to Brady's question. I agree with Mike that transfusions have kind of got a bad rap since we've had EPO. I think there will be a

behavioral offset. Even if transfusions are bundled into the anemia management of a new composite rate, I think there will be much more scrutiny in terms of what is the most cost-effective approach to refractory anemia. Right now we're throwing all this EPO at these patients profitably because there's some money to be made there as well. I think once we all consider what the most cost-effective approach is, we're going to have an increase in the use of transfusions. I think it's inevitable.

DR. HIRTH: The final thing standing between us and lunch is just that I wanted to summarize with what are the outstanding questions for case-mix adjustment to kind of give you something to think about over lunch and come back to our discussion afterwards.

The first one comes out of the last slide; what do we do about this sort of consistency of EPO use over time, the sort of EPO dose response measure that we've kind of loosely calculated here and its explanatory power, or more generally, prior utilization measures. Our basic model had one prior utilization measure which is were you hospitalized the month before, which was an important predictor of cost in the current month. Should that be

there or not? Should other measures be there?

There were some of the issues that Jack raised at the beginning. Should average payment be based on current practice? All of our data is based on current practice; 2003 practice -- I shouldn't even say current practice -- or some indication of what a clinically appropriate practice might be.

What about extreme values? What other types of risk adjusters might we want to collect? How do we define and pay for the outliers? Are there some clinically and plausible values for EPO? We caught that $320 per session for EPO and iron spending in our sort of arbitrary, trim off the top, 1 percent of most expensive months and say what happens for outliers. Is that a reasonable outlier measure? Are those clinically reasonable values? These are all things that we should come back to when we have a chance after we eat.

CO-CHAIRMAN RUBIN: Before we adjourn, I have just maybe one or two questions I'd like to ask of you.

DR. HIRTH: Sure.

CO-CHAIRMAN RUBIN: What other things did you noodle around with besides this EPO dose response? I mean,

here you have this mountain of information and you could have come up with all kind of ideas, some of which you may have gathered from the work you've done with the DOPS program, et cetera. You've been doing this for quite some time. What other things did you look at that might predict cost?

DR. HIRTH: Well, one of the things we looked at was hematocrit. We have in the model the baseline hematocrit, the start of ESRD therapy, but we also had the more current measures of hematocrit, which were quite predictive of cost. They had a pretty similar effect on cost as adding the EPO dose response measure.

We have greater concern in terms of their proximity to current treatment and direct outcome of fairly current treatment. That's why we prefer the EPO dose response measure because that goes back six to eight months before the beginning of the year. So hematocrit is one of the things we kind of noodled around with. We're still kind of at the beginning stages in terms of building these models as we're really focused on the demographics and comorbidities and have just started looking at some of the utilization measures.

CO-CHAIRMAN RUBIN: Well, you showed us pretty convincingly that the demographic stuff is terrible. All of the things aside, an R^2 of less than double digits just isn't really good. Joe Newhouse -- the difference between less than 10 and 35 is -- I hate to use the word "significant" in this crowd, but 35 is what he argued is the absolute theoretical ideal of perfect case-mix adjustment; anybody has ever come close to accomplishing in practice. I'd like to at least lay that out there.

DR. HIRTH: I will say that our intent in looking at this prior EPO use, the bundles are dominated by EPO and Vitamin D. We haven't gone to Vitamin D yet, but I don't think we're going to see as much there as we see with the EPO use. By looking at prior EPO use, we thought this would be about as predictive as you can get of current EPO use. Whether or not we bring in other factors beyond some measure of what is being done for this patient, I think that this is one plausible upper bound on what's going to be achieved there.

CO-CHAIRMAN RUBIN: I don't disagree with that. What I was asking really was, did we see the best of 100 tries too come up with a good measure or did we see one of

three tries to come up with a good measure?

DR. WOLFE: It's closer to one of three.

CO-CHAIRMAN RUBIN: Okay.

DR. HIRTH: At the same time it's inclusive; it includes all of the factors. A more usable model would be less explanatory than this model is what I'm getting at.

CO-CHAIRMAN RUBIN: Yes. And I'm not being critical. I just want to know whether there's more gold to be mined or whether you felt like --

DR. HIRTH: Not a lot more is my guess. Richard was hoping for more, I think, but I don't think it's going to be there.

DR. BURKART: In extension of Dr. Rubin's question, in your face validity you said initial months on the RRT, females, larger patients, et cetera, predicted the higher dose. But yet I believe from both the DOPS data and USRD data, presence of catheter predicts higher need for EPO. Was that not looked for in your data?

DR. HIRTH: That was not looked for.

DR. BURKART: Would that be helpful to include that in the model?

DR. HIRTH: Let me leave that to the committee.

We didn't think of that as a case-mix adjustment; that's a practice pattern. We were even debating whether to bring in hospitalization as a predictor because that's also a consequence of the treatment at the facility. And the intent is not to adjust for what the facility chooses to do, but instead to adjust for the characteristics the patients bring with them inherently.

CO-CHAIRMAN RUBIN: Actually, Medicare uses a number of those kinds of things in their adjusting the payment for managed care, so it's not really off balance.

DR. EGGERS: Oh, I think it is terribly off balance. The *Washington Post* headline thing here, "Medicare pays more for poor care." Medicare decides that the more patients you have on catheter, the more we're going to pay for you and reward you for that; prediction aside.

DR. HIRTH: I was talking about hospitalization.

DR. EGGERS: Well, yeah, but we're not in the business of writing economic papers; we're in the business of coming up with something that is defensible.

CO-CHAIRMAN RUBIN: Okay. Dr. Owen, you have the last word before lunch.

DR. OWEN: Not a word, a query. Could you remind me? Did you guys look at the anthropometric attributes? I know you had it earlier on.

DR. HIRTH: Yes.

DR. OWEN: So you had BMI?

DR. HIRTH: BSA and BMI, low BMI indicators.

DR. WOLFE: We've also looked at weight. And wasn't weight slightly more predictive on the EPO component? Once you start bringing in other things, it's less clear which one is better.

DR. HIRTH: BSA and weight do pretty much the same thing.

CO-CHAIRMAN AUGUSTINE: Help refresh my memory. In the phase one report, you included adequacy in anemia? I remember the score being higher in the phase one report than we have in these analyses. Is that correct?

DR. WOLFE: We were there explaining facility level variation and composite rate costs per treatment and that had a series of control variables, including things like facility size that were quite predictive of costs. The incremental R^2 of the case-mix variables on top of those facility level controls was actually smaller than we're

finding here. The overall predictive power was greater. It was entirely different variable. This is at the facility level.

CO-CHAIRMAN RUBIN: Great. Thank you for that illuminating discussion, and I think it will give us plenty of grist for our meal, after lunch, which will occur from now until 1:15. We'll reconvene at 1:15.

(Whereupon, there was a brief lunch recess.)

CO-CHAIRMAN AUGUSTINE: This afternoon's session, I will be following my colleague here and trying to do the best I can to follow his lead of keeping us on time. I will be moderating but this will really be a group-led discussion. We do need to start answering some questions and providing some additional guidance to the CMS staff and also the contractors.

One thing I was reading yesterday was some old dimming quotes. One of the ones I like is, "The two most important things to know are the unknown and the unknowable." We're kind of conquering those little by little, not only due to the good work of KECC and CMS but also Nancy Ray and her team at the Medicare Payment Advisory Commission and NIH with regard to a lot of our

work in daily dialysis. But still even though there's a lot of information that is known, the unknown is what we're trying to come up with today in this group. So I'd like to concentrate on things we do know, based on the presentations we've had this morning, and to kind of go ahead and funnel our conversations.

I remember there was a discussion this morning about the MCP payment and the vascular access services bundles. They were labeled 2A and 2B. I'd like to hear from the group, but my personal perception was that, just looking at the administrative morass of implementing those would be very, very difficult to do in a timely fashion. Also, for example, with vascular access, that is something that we could approach from a pay-for-performance perspective that would achieve many of the same goals in an administratively more simple fashion. So I'd like go ahead and have a quick discussion on Bundles 2A and 2B, and if it's agreeable to the group, then we can start focusing our efforts more on the 1A through 1D bundles.

CO-CHAIRMAN RUBIN: Could I make a suggestion, maybe to just sort of shape the discussion, that I'll put on the table that we should not include vascular access in

the bundle, then people can talk pro or con just to focus their thoughts.

DR. LAZARUS: We're starting just with vascular access.

CO-CHAIRMAN RUBIN: Yes, sir. You wanted to talk about the other one?

DR. LAZARUS: I want to talk about the other one.

CO-CHAIRMAN RUBIN: Okay. I'll put a similar statement on the table. We can do the other if you'd like.

DR. LAZARUS: If you want to separate them --

DR. OWEN: I think they should be separated.

CO-CHAIRMAN RUBIN: Yeah, I agree.

CO-CHAIRMAN AUGUSTINE: Well, we'll talk about the MCP first.

CO-CHAIRMAN RUBIN: Well, I'll say that the MCP shouldn't be included in the bundle.

CO-CHAIRMAN AUGUSTINE: That's almost like a motion.

DR. LAZARUS: If we're going to have quality outcomes in this bundle of any sort, and particularly if you're interested in a P4P in this bundle where there are outcomes, I don't think you'll get any provider that will

participate in this demonstration without having the physician in the bundle, or at least in lock step with the outcomes. It would be suicide to do this without control of the person that makes the decisions on all the outcomes. You have a problem if you want to leave the MCP out. I think your providers will not jump in.

CO-CHAIRMAN AUGUSTINE: I'd like to hear from some other board members.

DR. WISH: I agree with your philosophy. I see a tremendous potential for abuse however, not so much of the demonstration, but if this is rolled out as public policy, in terms of the MCP becoming a way for physicians to be recruited by a dialysis chain; that is you sell to the higher bidder. I fear that the MCP would be less of a tool for payment of performance as a tool for payment for referrals.

DR. LAZARUS: I don't think that the provider has to control it. I just think that MCP has to be restructured with the same outcomes that the facility has to take. You have to have the same incentives, or you will not get anybody to do this.

CO-CHAIRMAN AUGUSTINE: And that is something

that the agency has been quite supportive of, is aligning incentives between practitioners and providers. The question is whether or not that's within the scope of this demonstration because this demonstration is for an expanded bundle for facilities.

DR. LAZARUS: I don't think if you put quality outcomes you will get anybody to participate.

CO-CHAIRMAN AUGUSTINE: Let me ask you a question, Dr. Lazarus. With regard to your medical director agreements and a lot of the feedback that you provide your practitioners presently, you provide high quality care. That has some impact on that.

DR. LAZARUS: Well, you have to cajole, you have to beg, you have to do all kind of things. If I have a physician -- and I have physicians -- that say, listen, I want to do a short time only because the competitor down the road is doing short time and I'm not going to get any patients, and he's got lousy outcomes. And I say to him, you need to get your KTOVs up. He says, sorry, I don't care; that's not my problem.

The same thing with anemia. There are some physicians who don't believe in giving iron, and they won't

give iron, and they have very low outcomes. So despite the way that we manage now, I don't have any skin in the game if they don't participate. When you start making my payment relative to the outcomes, and I can't control those outcomes, then I don't want to play in that game.

DR. OWEN: I was just going to comment that if cajoling, begging, best medical evidence, monitoring we're going to work, why haven't they worked? Relying on changing the reimbursement to a Dr. Lazarus and that component of the provider I think is not going to work on the physician piece because you haven't changed the physician piece. That's in many ways where the lesion is.

I don't think the lesion is with the providers. I mean, it's not a sound business model to not take care of my unit of income, and that's the patient. So I think any provider who is mercantile is going to absolutely strive for that, in many ways, validating what you and CMS have said for so long. And that is that there is a natural tension right now because the reimbursements are not aligned. I recognize the administrative challenges of trying to bundle the MCP in that. I also recognize how challenging it will be to my colleagues in terms of

employment models, but I just see no way that we can continue to use a provider as a surrogate, and that's what's being described here, without including the MCP in there. By the way, there's a substantial precedent for physicians working for a provider, whether it's a resident physician, whether it's a managed care organization, whether it's a hospital, and they do work.

MS. ROBINSON: I thoroughly agree with the outcomes argument. I'm about to argue both sides of it. I think that there are still patients who don't see their physicians, and the facilities are livid about that, but they can't make the physician get into the facility, and that reflects poorly on the facility and ultimately reflects poorly on a patient.

On the flip side of that though, I would want to ensure that the patient-physician relationship is able to continue and that it is not the facility practicing medicine, but it is the patient working with his physician to do treatment options, medications, whatever the case may be.

CO-CHAIRMAN AUGUSTINE: Other comments?

DR. BURKART: Yes. I think as a physician, not

as a medical director, I have red flags having the MCP be part of the bundle. However, as a medical director of dialysis units, I think there are reasons where we need to realign the payment. Now, when I say realign, I'm also saying as medical director that sometimes I'm not so sure I can get the facility to do the things that they need to do. So if we're going to do pay-for-performance and we're going to have quality initiative, I think that the desires for the physician and the facility need to be realigned. Occasionally part of what's going on I think is that there needs to be a physician-driven, medical director-driven changes in what the facility does. Part of the payment has to be aligned for performance not only for the physicians, but for the facility I think. I don't know if you have to have the MCP be part of the payment to the facility, but we need to get the performance and the quality outcomes aligned for both the physician and the facility.

MS. RAY: Right. I just was going to add that was MEDPAC's recommendation, to implement pay-for-performance and that it be linked to both the facility payment as well as the physician payment.

MS. GREENSPAN: I want to add that I think if

you're worried about getting facility participation, the physicians might have a lot of concern about this being put into the bundle, and the kinds of access issues that Paula had alluded to earlier could be a problem. I think that having them as a pay-for-performance but not bundled would be generally it.

CO-CHAIRMAN AUGUSTINE: Well, that's another concern of course, is being able to, in a very short time frame, have a situation where a lot of nephrologists who want to be a part of this -- this is something brand new. I don't know if this is something that RPA has opined on and ASN and other major leadership organizations.

DR. OWEN: RPA has spent a lot of time thinking about this. I am not here as an RPA representative. I'm here speaking as Bill Owen as an individual. And my stand's, quite candidly, is opposed to what the RPA had stated previously. I'm comfortable with that because, quite honestly, the current RPA stands I see as incongruous with what the ultimate goal of this demonstration project is. The ultimate goal is to improve patient care. The penultimate goal is to develop a model that will do it in I think, quite candidly, what's going to be a cost neutral

way to the system.

CO-CHAIRMAN AUGUSTINE: So the advantages to having the MCP services involved in this expanded bundle are primarily with regard to the pay-for-performance area. It would water down the case mix part of the bundle because there's such little variation in MCP services, basically right now either yes or no, based on the data that we have. So it would make the case-mix models a little less accurate if we included MCP services in there.

Now is that a correct statement, Dr. Wolfe?

DR. WOLFE: It would lower the R^2 at the total bundle, but at the same time, compared to the current system which is a flat payment, it wouldn't be any different from what it is now. We wouldn't be able to case-mix adjust it, and it's not case-mix adjusted right now.

DR. LAZARUS: But it should be.

DR. WOLFE: It should be, but we can't because we don't have any cost reports from physicians.

DR. LAZARUS: I understand, but you make rounds in the unit. You see all the patients and you get paid for the round. You spend all your time with sick patients when

you do those rounds. So it's not a reflection of what the doctor does. And clearly, you spend more time taking care of a sick, legless diabetic than you do an 18-year-old healthy woman.

DR. WOLFE: One way to handle that would be to do a case-mix adjustment based upon separately billable services, and then assume that physician time was proportional to the separately billable services that do vary, according to our measurements, by the same adjustment to it. It's very artificial, but it's probably better than doing nothing.

DR. LAZARUS: What services are those?

DR. WOLFE: EPO, Vitamin B.

DR. LAZARUS: Again, we have a problem with the weight. Bigger patients get more EPO, and you would assume that maybe that means that they're sicker patients. And they're not; they're healthier patients. You have to have a better way than charges and the claims data. It just is not the right approach I don't think.

DR. EGGERS: If one was to do something, take a different set of data to emulate what physicians have to do, I would go outside of that and base it on some sort of

hospitalization that would capture a lot of that time. I'm presuming that if monitoring a patient that is hospitalized a lot probably transcends to more time in the facility as well because we've got the same kinds of problems there.

CO-CHAIRMAN AUGUSTINE: The present postulation is that it would include just MCP services, but that brings the question to hospitalization. Some people relay to me that right now there is an incentive potentially to hospitalize patients. Is that something that would be in consideration for a bundle just like the MCP services?

DR. WISH: If the purpose of this discussion about the MCP services is to try to align incentives, to try to optimize outcomes and make sure that the performance is appropriate, then I think it's a secondary argument in terms of whether that MCP payment comes directly from CMS or whether it comes through a bundle through the dialysis provider.

I think the real question is aligning the incentives and paying for performance as far as the MCP is concerned. If that's the case, then it has to be case-mix adjusted, not so much in terms of the cost and whether you align that with the dialysis facility costs or you look at

some other cost surrogate; that's obviously important. But I think a more important issue in terms of the case-mix adjustment for payment for performance is the comorbidities and the other things that drive whether or not a patient responds to EPO or appropriate therapy. I think in those cases you're really going to have to be looking more at process measures than outcome measures. Did the physician do what the physician was supposed to, more than did the desirable result get achieved. The physician is accountable for doing the right thing. It's much harder to hold a physician accountable for achieving the target result if there are barriers to that target that the physician can't control.

CO-CHAIRMAN AUGUSTINE: That's one of the major discussion points for this afternoon when we get into pay-for-performance. The first part of your discussion was probably more important or germane to this discussion, the fact that, yes, we all agree that their incentives should be aligned. How that occurs, you can either occur it through the bundle which could be administratively more difficult but within the scope of this demonstration or it could be outside, which is the position that CMS takes at

large in the practitioner community, but not within the scope of this, and would not be included in the RFP. That's the basic decision point that we need to make.

MS. ROBINSON: I think with the MCP, along with everything else that we need to think about, it is how does it affect the rural, the independent, and the smaller facilities. We have to keep that in mind, and will this make a significant impact on those facilities.

DR. LAZARUS: It should be exactly the same. I mean, whether you're a large chain or an independent, if you have goals to achieve and the person that writes the prescription and writes the order is not similarly in line, even for a small facility, probably more for the small facility, you have a problem.

CO-CHAIRMAN AUGUSTINE: Before we came back in here for the afternoon session, I made sure to write up there the aims, which is something we always need to keep mindful as we have our deliberations. I'd like to hear some more comments with regard to the MCP. We can either choose to include it in the bundle. It would be administratively difficult and more burdensome for us and also facilities, or we could choose to actually have

facility payment here and agree that we should align incentives, and make that recommendation to CMS, and that CMS is evaluating its physician fee schedule. That recommendation would be on the record.

DR. LAZARUS: If a facility elects to participate in this demonstration and that facility has six doctors that practice there, and your scenario is that CMS is going to take that six doctors and allow them the same quality outcomes as for the facility, how do you get the physicians to all agree to participate?

CO-CHAIRMAN AUGUSTINE: One of the issues we're going to have is how we're going to administer the initial method. That's the only regulation that we have that we could do this. An initial method, for those of you who may not know, is basically an artifact that's been around since 1983, where if every single one of facility physicians choose to build an initial method, they can build through the facility's composite rate. I don't know if it's add on. I guess it's an add on. It's never been administered. They would get paid an equivalent of about 130 bucks a month. That would give us some flexibility and we could change the numbers in there. But basically they agree to

get an add-on payment to the composite rate for all the physician services in lieu of the MCP payment.

That's something that is not used. We don't have the administration internally to actually administer that presently. A lot of questions come to mind with regard to case mix, with regard to outliers, and with regard to potential start issues that would be very difficult to address in the next six months, which is when we need to have this thing implemented. According to MMA, it's January 1st of next year. That's somewhat the reasoning for my kind of hesitation to adopt it even though I agree with it in principle, is I can just see it being very difficult to administer from an agency perspective.

MR. BACHOFER: Just a comment. I did hear one sort of distinction, Brady, that you were starting to build on. That is the difference between do you take the MCP amount and bundle it into the facility payment or do you ask a slightly different question, which is given whatever incentives you've created through the facility payment, how do you create a parallel sort of incentive through whatever method it is that you're using for the physician?

One method, just off the top of my head, I can

think of for doing that would be within the design that could go out to create an opportunity for those facilities that are interested in working with their physicians to do something along those lines to try to build the P4P thing around that kind of notion. Separate pools of money but similar kinds of incentives operating. That's something we would have to work out coming back into the next meeting of this as we come out of the P4P discussion.

CO-CHAIRMAN AUGUSTINE: So in other words, the answer resides more in the P4P piece I think than the actual bundle composition as far as MCP is concerned. Do Henry comments help that?

CO-CHAIRMAN RUBIN: I don't think so. I don't want to put words in his mouth. What Mike is saying is the degree to which physicians participate will clearly affect the willingness of any individual provider’s facility to participate in the demonstration. In essence, the ideal de facto position would be the initial method, i.e., 100 percent participation.

We could come up with the cleverest P4P systems that have all of the incentives built in that we have for the facility. If I look at that, I say this is very

interesting, but you know what, it's a demo, and I'm not playing. So just send my MCP check to my office and I practice in his facility. If he tells me I should use iron, I just say screw that; I'm just going to do what I want to do.

The issue here is the compulsion of participation. Earlier we talked about compulsion of patients to participate. Now we're talking about compulsion for physicians to participate. It's in my mind an open question.

For the record, it was an issue that plagued the managed care demo that we evaluated several years ago. It's just one of those design issues that you've got to put on the table. It seems to me that that's a variable that each facility is going to need to come up with in terms of their own dealings with the physicians that practice in the facility. It also gets a little complicated in that a lot of doctors participate at more than one facility for more than one provider.

CO-CHAIRMAN AUGUSTINE: What would you do with the initial method then? That was one of the things we thought about.

CO-CHAIRMAN RUBIN: Well, I think the initial method in the broader scheme of things is probably an impossible thing. There's a reason why it was never implemented. Paul earlier today admonished us to live in the real world. The real world is we ought to set some rules, do the best we can for a P4P that sets the incentives to be in lock step with the things we're asking providers to do, and then let's see who comes to the table.

It may well be that for a whole variety of reasons one of your facilities decides, if I get four doctors to represent 85 percent of my patients, it's worthwhile trying to do that. The other thing is that peer pressure might get another 2 of the docs to do what they're supposed to do. So you'll have one that you're always batting your head against the wall.

DR. LAZARUS: P4P is a parallel program. It's going to be side by side with this. If the doctor signs up for the P4P program and we develop the same outcomes, and he understands that he and I have to work together to get a percentage of hemoglobin up and KTOVs up, what is the guarantee that they're going to be in lock step and everything's going to be the same? Is that some assurance

that CMS will offer us?

CO-CHAIRMAN AUGUSTINE: Well, there's an incentive for them to work with you. In the same token, you do have medical director agreements --

DR. LAZARUS: There are very few quality outcomes in those agreements.

CO-CHAIRMAN AUGUSTINE: I understand that it's increasing.

DR. LAZARUS: Yeah, but there are a lot of eight and ten-year contracts a long time getting there.

CO-CHAIRMAN RUBIN: The answer to the question if you posed it to me is that's the way I would design it.

DR. LAZARUS: Are we designing a P4P as well?

CO-CHAIRMAN RUBIN: Well, we're going to talk about a P4P later on in the agenda, and I think that's where we need to take a stand on.

CO-CHAIRMAN AUGUSTINE: I just want to go on the record as saying, you disagreed with me, but you ended up in almost the same place that I was.

CO-CHAIRMAN RUBIN: I know, but no one's supposed to know that.

MS. CUELLAR: If the physicians are compelled to

participate in the P4P or in this project, it would be very convenient for him if he didn't want to participate, or her, to have no patients that would be interested in participating. I mean, if the patients can't be compelled to participate, and I don't want my patients to participate, they won't be participating.

CO-CHAIRMAN AUGUSTINE: Unless there are other discussion points --

MR. CANTOR: I'm fundamentally against the MCP being a part of the bundle just because it's too much power in the chains. There's got to be a balance here, and not just on a profit basis, finances, but also on the other side. I think to take virtually half of the physician's income and make that come from the chains is a bad idea. We need the balance.

CO-CHAIRMAN AUGUSTINE: Okay. I'm going to motion presently that we not include MCP services in the expanded bundle, but approach that through aligning incentives through P4P. Do I have a second?

DR. WISH: Seconded.

CO-CHAIRMAN AUGUSTINE: Any discussion? Any opposed?

DR. LAZARUS: And if you don't get the second part of that sentence accomplished, what then?

CO-CHAIRMAN AUGUSTINE: We can actually do a separate motion to actually make a recommendation as a board, but I think it's duly noted, and I think CMS is quite interest in the aligning incentives just as much as you are.

CO-CHAIRMAN RUBIN: I guess my amplification of that would be that we ask the staff to come up with a proposal for the July meeting that would meet the goals that we've just articulated, and then at that point you can do whatever you feel like you need to do. DR. EGGERS: Groups typically give a group recommendation?

SPEAKER: Yes.

DR. EGGERS: You've got a split here. We don't fall in the split, so you're not going to get I think a unanimous recommendation here.

CO-CHAIRMAN RUBIN: I don't hear anybody splitting.

DR. OWEN: Can I ask for a point of clarification in terms of what you described?

DR. EGGERS: We're not going to vote on it. If

we did, it would be a split vote.

DR. OWEN: I don't want to vote. I'd like a clarification of what you're describing in terms of what I'm seeing as checks.

CO-CHAIRMAN AUGUSTINE: We can do this in pieces. The first is whether or not the MCP services should be included in an expanded bundle.

DR. OWEN: You proposed a moment ago that it would be separate, so I'm now aligned with Mike in terms of P4P. Describe to me what aligned with Mike for P4P is because I've got a feeling that not everybody has the same idea of what alignment is around this table. So before I vote on something, I want to know what I'm voting on.

CO-CHAIRMAN AUGUSTINE: Let Henry describe what he was talking about earlier.

MR. BACHOFER: Actually, I just wanted to recall something that Dr. Rubin just said, that sort of directed the staff, if you were to create a way of aligning these things, what might that look like, so that that could then be addressed. We could spend time this afternoon -- but I'm conscious of the limited amount of time that we have -- about various possible ways of doing that. Some of

that we may actually have a chance to explore under the P4P discussion.

CO-CHAIRMAN AUGUSTINE: Let me reposit the motion. Our motion is that we not include MCP services dependent on this board's approval of a reported recommendation on aligning incentives between facilities and practitioners. Any comments?

SPEAKER: Are we voting or punting?

CO-CHAIRMAN AUGUSTINE: That's basically punting until we get a better idea about the P4P. But for the time being, we're going to stop thinking about MCP and expanded bundle. We've got a second. Do we have any further comments? Any opposed? Motion so passes.

CO-CHAIRMAN AUGUSTINE: Moving on, vascular access services.

DR. EGGERS: I will make the motion to exclude it because I think that all the problems that you have with MCP are multiplied a hundred fold in terms of incentives, definitions and everything else. Unless I hear somebody around here do a compelling argument for why we should include that in here, regardless of whether it's theoretically or practically a good idea, I would say that

that one should be tabled indefinitely. That's my recommendation.

DR. LAZARUS: I'm going to play devil's advocate although I'm not sure I agree with my position I'm going to take. This has clearly been shown to be the biggest problem we deal with, the most costly problem, and to put it aside is not to deal with the major cost issue that we deal with.

I understand it may be difficult, but if there is some incentive or motive to make the providers at least -- and I can't speak for the physicians -- to go out and be more aggressive about finding a surgeon -- it's not in the provider's interest now to go to a hospital, identify a surgeon, get a contract with that surgeon, and find a good surgeon that will do what you want. It's just not in my interest a great deal.

This would align the provider to go out in the community, find a hospital, find a surgeon, find somebody, get transportation to go get their access fixed. If the patients that are not covered under Medicare are subsequently covered, if that comes about, then there's a larger pool of people from the pre-ESRD population that

would interest providers.

CO-CHAIRMAN AUGUSTINE: We have had discussions on that, but from my understanding of the purview of this demo or this expanded bundle, we can play with payment policy but not exactly with eligibility. So we can't reach before someone's eligible for Medicare.

DR. LAZARUS: If it happens somewhere else with fistula first, and they get that accomplished in the meantime, you wouldn't take advantage of that?

CO-CHAIRMAN AUGUSTINE: That is something they're considering, and until that is done, that's a statutory change and that is very unlikely to happen this year.

DR. LAZARUS: I guess my point is that we not just take the major problem that we're having to deal with and drop it aside because it's going to be difficult.

CO-CHAIRMAN AUGUSTINE: I think everyone on the board is in agreement that vascular access services are very important. I think from an administrative standpoint what Paul is describing -- he's looked at this detail on numerous occasions in the past -- is that it's administratively a nightmare because there's so much overlap. But maybe we can make the same caveat that we did

for MCP, that we include it in P4P to align incentives with the nephrologists in the facility in P4P on vascular access. That may be the better way to approach it.

DR. LAZARUS: I don't understand the administrative problems. I mean, you're going to pay a provider a lump sum to take care of the access. There are no administrative problems. It's now my issue to go do all this.

DR. EGGERS: Including pay for all the hospitalizations.

DR. LAZARUS: Including all that. If the price is right, it will get done. You have people that will drive this and will go out and say, I can manage this. I can manage this surgeon. I can manage this radiologist. I can get me a surgical suite on Thursday afternoons in a hospital --

DR. EGGERS: -- supposed to do that?

CO-CHAIRMAN RUBIN: Nobody came to the party.

DR. EGGERS: Well, how about that? So they didn't come to the party then, but then --

CO-CHAIRMAN RUBIN: One group came to the party.

DR. LAZARUS: Well, I'm back to the price tag.

If the price is wrong, you're not going to get anybody to come.

CO-CHAIRMAN RUBIN: Can you just help me understand something? The dialysis unit, they don't make referrals to physicians without another physician --

DR. LAZARUS: No. My entire conversation still rests with the doctor being incented with me. If he's not by my side in any of this, I'm not interested.

CO-CHAIRMAN RUBIN: So that's the precondition that you're talking about.

DR. LAZARUS: Absolutely. I can't refer anybody.

CO-CHAIRMAN RUBIN: Right.

DR. LAZARUS: I've got to have a doctor with me. The physician has to be with me or I'm not interested in anything. And likewise, now I'm helping him. We're working together; we're trying to get this access fixed. Both of us are incented to do that.

DR. EGGERS: A fully capitated system because all of those things are related. Why stop at vascular access?

DR. LAZARUS: Well, that could be whether we ought to be talking about the other demonstration here, but that's not what we're talking about.

CO-CHAIRMAN AUGUSTINE: That's the question; how far along the continuum do we want to go to learn something that we're going to be able to implement in the program. A lot of what we're talking about is really more along the lines of what's in the current or soon to be demonstration that seem to be in limbo forever. Now it's limbo plus one; it's purgatory, which is more of a disease-management type model.

MS. MAGNO: It's capitation. I think just to characterize it as disease management short changes what it really is. It's a capitated model so it's the full range of services with disease management as one component.

DR. LAZARUS: I don't want to take care of CABGs and automobile accidents, but it's not unreasonable for me to focus on vascular access, which is a hybrid step in between the two I think.

SPEAKER: Other comments on vascular access?

DR. BURKART: If we include vascular access there may be some other things that are beyond the scope or the ability to influence not only the physicians and the facility. For instance, one of the comments was that if it was bundled, all vascular access procedures would be done

as an outpatient. Well, if you're in a state where you have to have CONs and you're limited as to what you could set up -- your cost -- you won't be able to influence the costs as much as you are in state where you could set up your own freestanding outpatients surgical unit, if you will, where you can do all these things.

One of the issues about vascular access is not only what the facility can control and what the physicians can control, but there are these other limitations and constraints that are put upon people that may vary geographically or by state also.

DR. LAZARUS: Is it reasonable or possible to have an option that you could do this demonstration without vascular access, or if you were in a city or a place where you thought you could this, you could opt to do it with vascular access?

CO-CHAIRMAN AUGUSTINE: That's something we can recommend. We can make a recommendation. I said earlier, because of the administrative issues, we would like to have as few options as possible. It makes it easier for us to administer it. But that's an option that we had looked at in the disease management demonstration that's currently in

purgatory and something we could look at here as well. Or it could be approached through some type of gain sharing. I mean, that's another way to approach it. Since vascular access is such a huge portion of hospitalization costs, some type of risk-sharing arrangement could be another way to get at vascular access management as well. There are a lot of different ways to approach this.

One thing I would like to do real quickly, Henry, if either yourself or someone from KECC could maybe run through some of the administrative difficulties that you've already kind of postulated for us in your presentation with regard to vascular access.

MR. BACHOFER: I guess the short way of approaching that is to provide an option. For example, we would have to then make modifications as part of the demo in claims processing systems for hospital services, physician services. We would have extensive changes throughout all of the administrative components. I frankly am very skeptical about our ability to make all of those changes and get them all in place in conjunction with the time frames for this demo.

In effect, we would be have to have the ability

for any patient that is enrolled in the demonstration -- when a claim is submitted that has services that are somehow, somewhere identified as part of the vascular access "bundle of services," that a denial would be put in. And the provider that submitted that claim would be directed to the dialysis facility who would then have to determine whether and how to pay for that service. We would also have to figure out an adjudication mechanism to say are you in fact obligated to provide for those services.

The farther go down the path of how it might work, it's a great set of questions and a great set of issues, but I don't know how we can make that happen within the time frames that we're trying to operate on for this more narrowly focused bundle.

CO-CHAIRMAN AUGUSTINE: So it would increase the burden to CMS, make it more difficult for us to administer in the tight timeline that we have. But it would also potentially significantly increase the burden to facilities, and then would in fact have to become somewhat of a claims payment shop. It may be a better way to approach it just like we talked about with the MCP,

approach it through P4P as opposed to expanding the bundle to include vascular access services.

Nancy, from MEDPAC's perspective, you've actually weighed in on vascular access services. You made a recommendation on this if I remember correctly.

MS. RAY: Yes, that the broader bundle should consider including commonly used drugs, laboratory services, as well as other kinds of services, vascular access services, and other Medicare covered preventive services, like hemoglobin 81C's, those type of services.

DR. OWEN: What do you do about cardiovascular disease? Do you bundle that in? Half the patients are going to have a heart attack or go into CHF. So where do you stop in terms of that definition of what services you include? I'm not trying to be glib. If I do it in terms of frequency distribution of events, it really opens things up.

CO-CHAIRMAN AUGUSTINE: You're asking three questions.

DR. OWEN: Yes.

CO-CHAIRMAN AUGUSTINE: Let's stay with where we are with vascular access.

DR. OWEN: Well, I'm just commenting in terms of the MEDPAC report, the statement of frequently occurring services.

CO-CHAIRMAN AUGUSTINE: You've said a consideration of vascular access, but have made no definite recommendation on vascular access?

MS. RAY: It wasn't in the recommendation per se, but it was in the language beneath the recommendation, that these are the services that should be thought about when broadening the payment bundle.

CO-CHAIRMAN AUGUSTINE: Thank you.

I get back to my original point. I think maybe kind of the same punting type language we used for the MCP we may want to use for vascular access as well, maybe to agree to not include it in the expanded this time, depending on some feedback, including some type of pay-for-performance for vascular access that aligns physicians and facilities payment being reported to us at our next meeting.

DR. LAZARUS: Can I just ask a question? Does the second part of his sentence resolve -- you're still going to have that problem in a P4P program, right?

MR. BACHOFER: The question that we'll have to address under P4P is what kind of incentives and on what basis do you provide the incentives? Are actually changing the method of payment, for example, for the surgical procedures? Probably not under P4P. But are we providing a way of creating incentives to move people in the direction of increased reliance on fistula? That's a different question and would not require a change in the way individual claims are processed.

CO-CHAIRMAN AUGUSTINE: And a lot of that infrastructure already exists with regard to the fistula first initiative and can be expanded it. Patency is much more than just having fistulas in place; patency is very key.

DR. OWEN: Mike, who's getting incentivized?

DR. LAZARUS: Who's getting incentivized when?

DR. OWEN: Is it the surgeon, is it the nephrologist, is it the dialysis unit in who's needling it? One of the problems I have about vascular access -- although as much as I'd like to embrace it, I just can't reconcile -- I don't know who on that team I am actually incentivizing and is taking ownership of the

vascular access.

DR. LAZARUS: Well, in the broad bundle it would be the provider. You're going to give me a set amount of money to deal with this problem.

DR. OWEN: Yes. I'm asking deeper in your organization. I'm now giving you some money. You tell me who's getting the money. Do I give it to the surgeon? The surgeon puts the thing in and the thing gets trashed in the dialysis unit because it's not needled properly.

DR. LAZARUS: Well, it's my business to make sure that all these work well. I mean, that's what I'm getting paid for. I'm going to have to find a good surgeon. I'm going to sign a contract with him that he's going to do all of my access. I'm going to give him a nice place to do it in. I'm going to guarantee him that I'm going to train the nurses to take care of him in an excellent fashion, and I'm going to get incented to do that.

CO-CHAIRMAN AUGUSTINE: I'm sure others have more to say on this. But one of the things we've learned is that everyone is responsible. One of the reasons why health care isn't working nowadays is because people aren't talking and there's not someone who's kind of in charge of

coordinating the care of that beneficiary.

One of the main recommendations in the Fistula First Change Package is that the nephrologist -- that's the whole discussion behind vessel mapping, which CMS opened payment up for this year, is that the nephrologist actually can do the vessel map and actually write a script recommendation to the surgeon that we've looked at this patient's vessels and we think these are two or three places we could but a fistula in. We are trying to actually have the nephrologists -- the patient is the quarterback, -- but it puts the nephrologist there coordinating the care for our beneficiaries again as opposed to no one being in charge.

MS. GREENSPAN: One of the differences though between the vascular access piece and the MCP piece is that there are real costs that you would have to transfer. You have to do more in mapping, more in patency status and that sort of thing and less in where that other money goes. So if we don't cut the money that's currently being spent on other aspects of vascular access now into the bundle, then there really isn't money to do the really significant things. We don't get to pick the first access because

those people aren't in, so there really is a very limited amount of performance you can even control if you don't have the money to do it, if you can't get paid for doing it. If you can't get that cash that you would save, you're pretty limited.

CO-CHAIRMAN AUGUSTINE: There is a requirement in the current composite rate. I hate that Ray Keane is not here because he talks to me about this every time we meet, about the monitoring, the different machines for monitoring blood flow and access and advocating that CMS pay for that on an ongoing basis, and whether there's the money up front to invest in that. A P4P might not provide the incentive for providers to invest in that type of technology. So if it was included in the bundle, there would be more new technology in that regard. If it's approached from a P4P perspective, there may not be that same type of incentive. So, yes, that's something that we need to be aware of.

DR. EGGERS: With respect to Mike's thing about getting the MCP doctors vascular access, buying into the program, that whole issue of not being able to do this thing unless you get all other actors buying into it, do we expect that the outcomes or the quality measures that we're

going to use for this demonstration are going to be any different than they already have? Right now, for instance, we expect them to get everybody to a KTOV of 1.2, right? And they're supposed to do that already. And they don't have that same buy in with the MCP. Somehow or another the system is managing to do that.

I guess I'm kind of asking Mike why is it that in this demonstration if we don't have all that stuff, it can't work there, when it seems to be working, more or less in some areas, in the general system already?

DR. LAZARUS: Well, it depends on what you're going to ask me to do. If you're going to ask me to go from 92 percent --

DR. EGGERS: But my question is what are we going to ask of them. We haven't even discussed that as part of the demonstration project. If the demonstration project greatly increases the bar, then I kind of agree with you, but I haven't heard that that's going to happen.

DR. LAZARUS: Why do it if you're not going to increase the bar?

DR. EGGERS: To save money, run a better system? I don't know.

CO-CHAIRMAN AUGUSTINE: Well, there's increasing evidence. CMS released a press release I guess a few weeks ago in regard to some preliminary findings from their premier demo that P4P is working across the board. My personal perspective is that it's a shame that P4P should exist in the first place, but that it is effective and something we should consider to explore, especially in those areas that are very troubling and imperfect for QI. For example, it would be more difficult to do it for anemia and for adequacy because we're already near the top of the bar. But in those areas where they're still not opting for improvement, P4P could be a strong motivator.

Other comments? Let's get back to vascular access.

Henry, one of the things I asked earlier is maybe a better description of what are the administrative difficulties -- I know you handled it earlier in the day -- with regard to including vascular access in an expanded bundle. Did you cover that? Mike, you were talking earlier about them being a claims payment shop basically.

MR. BACHOFER: I was actually just touching on

it. The issue is fundamentally how do you define that set of services, procedures, et cetera that are payable under current benefits but that would be considered part of the "bundle" of vascular access services? How do you differentiate those services that might be used for vascular access at one point in time but might have another use at a different point in time?

There's a whole series of questions there that you would have to then go through to be able to pull out of the data the specific billable services that would be related to the vascular access procedures that you are performing. It's I think doing that that is sort of the large challenge. Almost, actually, at some level I feel that that almost constitutes a demonstration in its own right in order to figure out how to actually devise an operational definition of what comprises a bundle of services related to vascular access, how to pull those out, how to price them, and then how to pay them. I know that it's a vague answer, but essentially how do you decide what's in and what's not. Once you've got that definition, you then have the other administrative issues of how do you then have to modify all of the existing claim systems in

order to process according to that definition.

CO-CHAIRMAN AUGUSTINE: Are there members of the board that would still like to consider vascular access in the expanded bundle if we approach it through P4P? Any comments? I move that we not include vascular access services in the expanded bundle but provide a report at the next meeting of this board with regard to recommendations on including vascular access measures in the P4P portion of this demonstration.

Is there a second?

DR WISH: Seconded.

CO-CHAIRMAN AUGUSTINE: Any comments? Any opposed? The motion so passes.

DR. WISH: Can I respond somewhat cynically to I think it was Paul. Yes, we should take some satisfaction in the fact that we've achieved these wonderful benchmarks in terms of adequacy and anemia, but that's because we've essentially had unlimited resources to throw at them when we're in a fee-for-service environment. I think the change in the paradigm, where all these things are will profit centers become cost centers, makes it a whole different playing field. Even maintaining where we are now is going

to be a challenge, never mind getting better.

CO-CHAIRMAN AUGUSTINE: One point that I think is kind of inferred but never explicitly stated is that all of these pieces go together; the composition of the bundle, the update mechanisms, the consideration for new technology, pay-for-performance and minimum standards, i.e., the conditions for coverage, they all work together. They all impact each other.

The first directive is -- do no harm -- if we move to a bundle environment, we need to ensure our beneficiaries are still receiving high quality if not higher quality care and putting guards against some utilization. So we would need to be sure that at least in the recommendation and the proposed rule for the conditions or coverage to actually put some guards in place and also require data to be submitted to us on an annual basis. That's the proposal. But also P4P could help incentivize people to kind of reach for the bar so to speak. All of these things fit together, and that's kind of something we need to keep in mind.

Other comments?

DR. OWEN: I have one with respect to the IOM

maximums. We pat ourselves on the back for the improvements we made. It took an awfully long time. And number 3 up there is the timeliness, and a lot of this stuff is not dependent on biologic variability. The patient cohort didn't change; the behavior of the practitioners changed. And it took, quite candidly, over five years. That's an awfully long time.

CO-CHAIRMAN AUGUSTINE: I also want to comment. One of the things I give this community, our community, a lot of credit for is the CPMs, the core indicators. A lot of the work that Network 9 and 10 have done, we have been leaders with regard to quality measurement, and that's something Dr. Straubb -- who I hope will be here later today -- and myself, and many others have made sure to tout at every turn for CMS, is that this community has been leaders in many regards.

Of course the response that people tend to give me is, well, we're leaders; when are we going to get recognized? And number two, I don't know if I really want to be a guinea pig that much more in the future? Needless to say, there's a lot of leaders in this program. There's so much opportunity that I'm kind of excited about the

future, and having people at this table discussing it makes me feels very good about where we're going to go.

One other comment I really wanted to address before we kind of move more to bundle composition or trying to hone down on a particular bundle further is for this board, we have really heard -- which is a little surprising to me -- very little about PD versus hemo. One of the things I learned in my research days is that those are vastly different populations. As much of a policy person I am myself, I like to treat them equally so that PD is incentivized. Once you get into case mix and what not, that gets administratively burdensome. So I think we need to have a recognition and recommendation that we treat PD differently than hemodialysis. I think that's something I would like for this board to discuss.

Any further comments?

DR. LAZARUS: What do you mean by that comment "treat them differently"?

CO-CHAIRMAN AUGUSTINE: Well, as far as the payment system is concerned, the case mix will be very different between the two of them. I anticipate that the payment amounts, the dependent variable, would be

significantly different because PD patients don't have access to the same level of services, at least from receiving iron and Vitamin D for example, that in-center hemodialysis patients have. But the case mix will look very different I think as it was described by Richard earlier for PD as for hemodialysis.

MS. CUELLAR: Can I make a suggestion? When you're talking about PD, maybe you refer to home dialysis because there is a small population of home hemo, and they are at the same risk as a PD patient.

CO-CHAIRMAN AUGUSTINE: There are times I refer to it as home and people get confused, and times I refer to it as PD. I think it's either in-center or not in-center; I mean home. When we're talking about home the profiles are vastly different, from all of the different home modalities, as opposed to in-center.

DR. LAZARUS: So you're suggesting that a dialysis unit would enter this demonstration only for the in-center hemo patients, and if they have a large PD program, they would have a separate demonstration; they could opt for either one, and you would not put that as one entire program?

CO-CHAIRMAN AUGUSTINE: This isn't a recommendation. Actually, I would like to hear this out more. But the payment would be different for PD patients than it would be for hemodialysis, and it would reflect the average level of PD patients per month or per session across the country with certain case-mix factors that will differ from PD to hemodialysis.

DR. LAZARUS: Then your suggestion is it's going to be lower or higher?

CO-CHAIRMAN AUGUSTINE: It would be reflective of what an efficient provider would provide for PD.

SPEAKER: You're talking about the composite rate; it would be 40 percent as much.

DR. BURKART: But is that difference truly related to need or availability? What drives that difference? I think if we're going to pay differently we have to know what drives those differences. Is it that the PD patients need less or they're not given the same amount because of access to care?

CO-CHAIRMAN AUGUSTINE: Or all the above.

DR. BURKART: Or all of the above. If there are differences that don't have to do with patient care, we may

be subliminally preventing access to care. If we change the payment for reasons that have nothing to do with medical outcome or medical need, we may affect who does the different therapies.

CO-CHAIRMAN AUGUSTINE: I agree with you completely. That's why I'm saying that we need to be much more thoughtful on this issue. I think all of us agree that home therapies are not used near as much as they should, and there's a huge amount of opportunity there. That may be something that could be looked at in P4P as well, not that P4P is a panacea. But paying the same for hemo and PD, considering the fact that they're very different populations, is something that's kind of hard to justify.

MS. ROBINSON: I would just be really concerned about anything that we do that would not allow patients to know about home therapies. I mean, it's bad enough right now for patients to learn in certain facilities. If we're not going to help to get the home therapies out there, that's detrimental to patients.

CO-CHAIRMAN AUGUSTINE: I agree completely. CMS, Congress, and everyone has basically weighed in on this

issue of MEDPAC. We've all said that we would like to create an environment where PD can grow. Ironically, the payment system, which CMS administers, has not done that over the past years. Part of that is congressional, statutory, part of that is CMS.

We'd like to have an environment where we can have an environment that fosters home therapies. We've got a lot of opportunity for improvement, and we need to think about how we can do that in this demonstration and recognize the uniqueness of the home program, but also provide an environment where they can be incentivized as well without tying them to hemodialysis. They're very different populations.

DR. BURKART: For instance we have a composite rate for the treatment and then we have rates that you pay for the use of drugs and layouts. A lot of what happens in hemodialysis is related to these add-ons, what we would propose to be in Bundle 1A, 1B and 1C.

In PD or home therapies we haven't had so many of those opportunities, but there have been innovations in home therapy; daily dialysis, new dialysis solutions for PDs. And yet those things are in the composite rate.

I think if we're going to say that we need to do something different for home therapies, then we have to start at square one I think and look at the therapies and what the therapies actually are. We're willing to come up with Bundle 1A or 1B based on what we were reimbursed in 2003. We're just picking 2003; we're not picking 1995; whereas what we can do in our home therapies is based on the composite rate, which there's been no really resetting.

If we're not able to use the separately billables and we want to treat them different, I think we have to be prepared to start from square one and see what does it cost, what are the costs, and look at it completely differently because we've not been able to have any effect in what we do that comes under the composite rate in the home therapies.

CO-CHAIRMAN AUGUSTINE: Actually, you raise a very good point. In part, one of the reason why we're interested in expanded bundle is that our payment policy actually has an impact on practice patents. For example, there's not a lot of flexibility. There are a lot of providers out there that would like for a certain subset of their patients to do more frequent dialysis, other types of

modalities which are not really amenable to our current payment system. That's one reason why the expanded bundle provides a little bit of flexibility, like a monthly payment or a weekly payment, whereas you can choose which frequency and duration you would like that's in the best interest of the patient. So that is something we need to consider.

Now, how we do that is something I don't have the answer to. KECC, if you have kind of looked at home therapies, PD. What have you learned above and beyond potentially what you raised today on the few slides that we saw?

DR. WOLFE: We have not looked at home therapies other than PD really in any detail. The bills come in, to a large extent, through supplies rather than through the dialysis center. It's more episodic as those supplies come in. It's not as evenly shown and it's harder to know if we've got everything. I'll say we're less confident about our ability to know the right level of payments that are being made for those patients.

DR. EGGERS: The vast majority of the tables that we saw today -- I think it was parallel bars and $103 or

whatever it was -- did that include Type 1 PD patients?

DR. WOLFE: No.

DR. EGGERS: So that was all hemodialysis. Well, in-center hemodialysis.

CO-CHAIRMAN AUGUSTINE: One of the issues we have general -- I don't know if it's OIG or GAO. They found that Method 2, even though it had good intention, did not achieve its intended purpose, which was it would lower cost sharing for our beneficiaries, and it did not achieve that. In the aggregate, actually patients paid more under Method 2 than they did under Method 1.

There have been some changes in the program of late as far as instead of there being a package of services in Method 2, actually having people bill them separately and have helped out there. From an administrative, oversight perspective, Method 2 is very difficult because you've got another set of contractors to deal with. You've got FI, carriers, and now the DMRCs. Doing policy changes with another set of contractors is difficult, number one. And number two, from a quality perspective it makes it even more difficult as well because there's kind of a break up of who actually is in charge of the patient and who's held

accountable. So Method 2 is something that I would recommend that we not use for this demonstration.

CO-CHAIRMAN RUBIN: I have a few questions that I'd like to pose to the people at that table over there just to expose my ignorance here.

If we were to ask you for the July meeting to prepare data that would reach to the cost of peritoneal dialysis and/or home hemodialysis, could you do it with any degree of confidence?

SPEAKER: You said cost. Do you mean cost?

CO-CHAIRMAN RUBIN: I meant Medicare allowable cost, or payment, yes. Actually, not actual payment; it's what would be allowable.

MR. BACHOFER: I think the short answer to the question is that there are some things that could be done fairly readily and there are some data that are already included in the notebook that you have. This actually is comparing HD to PD. The numbers across the bottom, all odd numbers are drug amounts -- I'm sorry for the lack of formatting -- and all even numbers are lab test amounts. Those are the three major bundles. So 1 and 2 are bundled 1A. Numbers 3 and 4 are bundled 1B, and numbers 5 and 6

are bundled 1C.

Just very quickly and very graphically, what this is suggesting is that there is an enormous difference in the per month use of EPO, iron and Vitamin D, which is really the first set of bars there, PD versus HD, the blue bars being PD and the reddish bars being PD. If you go across the rest of them, particularly in lab tests, there's very little difference in the average cost per month, or average payment amounts, or max per month if you will, between the two categories. It's very largely driven by the first category of drugs.

The question that that leaves me with as I look at that is, is this because PD patients are being under-treated for anemia and the other things that they receive these for? Is it because they have lesser need? Is it because that need is being more efficiently met? We can't, I don't believe, answer any of those questions out of the data that we have in terms of the raw claims data.

CO-CHAIRMAN RUBIN: You can't? You don't have hemoglobin and hematocrit data for PD patients?

MR. BACHOFER: We could try to construct some measures like that.

CO-CHAIRMAN RUBIN: Wait, wait, wait. I'm sure you do have that.

DR. WOLFE: We do have that, yes. We could try to put something together.

CO-CHAIRMAN RUBIN: So can you take Database A and Database B and switch them together to answer the kind of questions you're asking?

DR. WOLFE: I heard several different issues being asked here. We can address whether hematocrits are being achieved, and the short answer is, yes, they are being achieved.

CO-CHAIRMAN RUBIN: Right.

DR. WOLFE: I think what Henry was referring to is we aren't sure that we're capturing all of the drugs there because we're only getting the IV drugs for the PD patients. I've understood that some of these drugs are not giving IV to PD patients but are taken orally.

CO-CHAIRMAN RUBIN: That's correct.

DR. WOLFE: So there's a substitution going on here and we don't capture those other drugs, which is I think what Henry was getting at.

CO-CHAIRMAN RUBIN: I understand that. But we

could have enough elements so that if we chose to have a PD bundle, we would know what we had in a base and what we might choose to put in. If we decide that one of the things we want to do is incent people to use more PD, we could align that dollar amount in a way that we think could achieve it.

In other words, what I'm saying is that right now, today, we don't seem to have actionable data. At least I certainly don't feel we have actionable data. What I'd like to see in July is the development of some actionable data so that we can think about how we want to deal with this whole issue since my understanding is that there's a movement afoot to try to get more people to go home, or at least start at home, whether it's PD, or home hemo, or whatever. But right now I don't see how we could do it.

DR. EGGERS: I make certain assumptions here. One is that OMB isn't going to allow CMS to do anything that isn't payment neutral on the whole thing. But if you were to mush them together in the analysis that you have right now, and you include all home patients -- home patients is 7 percent of patients. So you have a weighted

average really of those two bars there. Give 7 percent of your weight to the blue bar and 93 percent of your weight to the magenta bar there, and your bundle payment 1D, whatever it is, is going to shrink a little bit, and you could apply that to all patients. And then the facility gets a little bit less, but has all patients treated the same. That's what's going to happen when they crunch the numbers, as opposed to embedding in the payment system that difference there, assuming that it's correct. And I'm hearing now a great deal of enthusiasm for that.

DR. OWEN: I think we're probably comparing fruits, but are we comparing apples and oranges? First of all, isn't the EPO administered subcutaneously, and we're comparing an IV versus a subcutaneous route of administration? Secondly, I may be in error on this, but I don't think the percentage of patients achieving benchmark hemoglobins is the same, so are you going to forecast that out? I'm just saying, I don't think you can use this data to try to rate set for one unless you change the rules for the rate setting of the other.

MS. CUELLAR: And the same for the iron studies on those patients, and the calcium phosphorus, and the

PTHs, and all of those issues. Those patients are taking oral medications or not taking them at all, more likely, more than likely not getting the drug at all.

DR. EGGERS: What's your solution in terms of incorporated PD patients? Pay more for them?

DR. OWEN: I don't know, Paul, because I don't know if it's linear. We talked about dose response scores here. I don't know if it's linear or not. I guess what I'm saying is to use historic data to try to rate set when my benchmarks aren't being met scares me.

CO-CHAIRMAN AUGUSTINE: Especially when the Part D benefit is going to be coming on line at the beginning of next year as well, which will include coverage for those oral drugs.

DR. EGGERS: But we don't know that EPO isn't used 30 percent higher than it should be, right? So why are we embedding that into the new system? Why don't we just say, well, there's way too much EPO; we ought to cut back like 30 percent before we bundle it in there? You don't have that argument either.

DR. LAZARUS: This is not a financial argument; it's a how to argument. You can't give IV iron and you

can't give IV Vitamin D to somebody that's at home. Unless we figure out a way to do that medically, technically, it's not payment. You can give me all the money you want. The patient cannot give IV iron at home and they cannot give IV Vitamin D at home.

DR. EGGERS: So what's the solution here? We just eliminate home patients from the payment system?

DR. LAZARUS: Well, I thought that was the question.

DR. EGGERS: Well, that's why I'm asking you.

DR. LAZARUS: They're much harder to do, and that's why I'm asking are they going to be in the whole group or are you suggesting they be done separately?

DR. EGGERS: I'm suggesting that we have one rate for patients, that we mush it together somehow, and let the facilities determine how to allocate resources and treat their patients just like they do now.

DR. LAZARUS: Well, that will get more people on PD probably.

CO-CHAIRMAN AUGUSTINE: Other comments? Nancy, I'd like to hear from you?

MS. RAY: I think from MEDPAC's perspective we

recommended that the payment bundle be brought in and efficient providers' cost should be adjusted for factors that affect efficient providers' cost, including the modality. I think when you think about setting the one rate as Paul has suggested, clearly that's one approach, and that is a rather substantial incentive payment if you were to think of that as terms of pay-for-performance if you're trying to promote home dialysis.

Another way to promote home dialysis is to set the different payment rates based on efficient providers' cost. I think Brady has pointed out that the case mix of patient characteristics probably differ from the home population to the in-center, and so that would again be a reason to think about setting up two different payment rates. But again, Brady's point, not that pay-for-performance is a panacea, but I think when it's linked to those measures where you really want to see improvement, it should lead to improvements of quality, one being vascular access, another one perhaps being here in home dialysis. But you're potentially talking about -- and people can correct me. But on a monthly basis there's about a $600 difference between home patients and in-center patients. I

mean, that is a huge --

DR. EGGERS: $600 in what?

MS. RAY: Per patient per month difference in the broader bundle between in-center patients and home patients.

CO-CHAIRMAN AUGUSTINE: This is specifically PDHD.

DR. BURKART: Perhaps one way we can help facilities be efficient and reward them for efficiency is if you do have the same payment. Some patients will not be able to go home and will cost more money; some people will be able to go home. And if there's an incentive for people to go home -- I'm approaching this from the system we live in today, how we're paid today.

If there's an incentive for patients to go home, then facilities will be rewarded for efficiency. So if part of the bundling is it increases the amount of money that is paid per treatment equivalent, whatever therapy you're on, and it cost less to go home, that's part of the incentive to get patients to go home.

I just have to add anecdotally, there is restriction to care. We have patients that come from many

miles away to our unit because they cannot do PD or home dialysis at the unit they're at; it's not offered at their units. So we need to do something to change that.

MS. ROBINSON: We're in effect taking away a therapy choice for patients by not including home therapies, and I think that's wrong of us to even start doing that. Studies are showing that home patients have better outcomes, have less hospitalizations, require less EPO. I mean, why would we want to stop promoting that? Those patients who want to take it home have every right to take dialysis home.

CO-CHAIRMAN RUBIN: We wouldn't be changing current law at all.

MS. ROBINSON: No, but if you're going to do a demonstration project that only shows one choice, where is that going to lead us? I think that we have to have an opportunity for choice. And then how are dialysis facilities going to actually participate if they have a PD program? They're not going to be able to participate or their PD patients won't be able to, in the demonstration project.

CO-CHAIRMAN RUBIN: Well, depending on how you

view the demonstration; we've heard both views. During the day that's either a good thing or a bad thing. It's hard to know. There's no question that if we want to incent people to choose the home option, we can do what Paul did. I might point out we tried that 22 years ago, and it was a dismal failure.

DR. WISH: Bill raised the question in terms of whether we're comparing apples to oranges in terms of benchmarks for anemia and PD versus hemo patients. I have the 2004 annual report of the CPM on my computer. It's not been printed yet, but I have it. This is fourth quarter of 2003 data. Percentage of hemodialysis patients with hemoglobin greater than 11 was 80 percent; PD patients with hemoglobin greater than 11 was 82, so they're pretty close.

MS. GREENSPAN: I just wanted to ask about efficient providers. Are those providers who need the quality benchmarks? You would be very efficient economically if you don't give any EPO or iron in terms of a home-based.

MS. RAY: By efficiency, we mean low cost, high quality. I just wanted to be clear. I'm not suggesting that the demonstration included only in-center patients.

What I was suggesting is that there should be some discussion of setting one payment based on the efficient provider cost for in-center hemo, another one for PD, and perhaps using pay-for-performance as a mechanism to incent home dialysis.

Just picking up on something that you said, that there have been studies that have shown that patient satisfaction is better for home patients than in-center patients, that could be something that is measured and that is perhaps is linked to pay-for-performance, just as something to think about.

CO-CHAIRMAN AUGUSTINE: Thank you for summarizing my comments from earlier in a much better fashion than I did. I think that we're going to need to discuss more. I think it would be helpful, as Bob kind of mentioned to Michigan, if you could come back to us with some more detailed information on a potentially separate payment for PD home patients, and bring that back to the next meeting. Does that sound like a recommendation that we are comfortable with?

DR. EGGERS: Unless you want this demonstration to be an in-center hemodialysis demonstration only -- and

my guess is that Congress would kind of wonder why you're doing that -- I would direct them to do exactly that, but think about the incentive there. If we don't lump them together -- like I said, I realize that the composite rate didn't do what we were supposed to do. But if we set up something right now with two payments, one of which is going to be only 40 percent as great as the other one, we certainly will be getting more incentive to home dialysis.

CO-CHAIRMAN AUGUSTINE: I just want to make sure we're still clear. This board directs CMS, and then CMS will direct contractors.

DR. EGGERS: I understand.

CO-CHAIRMAN AUGUSTINE: And that goes back to Nancy's astute comment on P4P. You may pay them based on efficient use of resources, but then try to incent based on P4P. Of course, how you incent people to have patients on PD, which is kind of a clinical criteria, is a difficult thing that we'd need to tease out.

DR. EGGERS: Again, we can probably all agree that we don't want to do something that disadvantages home dialysis.

CO-CHAIRMAN AUGUSTINE: So the recommendation

stands, that we'd like to hear more about home therapies from Michigan at our next meeting?

MR. BACHOFER: Okay.

CO-CHAIRMAN AUGUSTINE: Okay, that sounds good.

As far as the four remaining bundles, 1A through 1D, I don't think we're going to have the time today, because we're almost near the end of this session, to pick a particular bundle. But I do think we need to agree that we need to move to a bundle, not necessarily choose which one it is. This isn't going to be a demonstration where we're going to have two or three options. I think we need to agree that we're going to choose an option and go with it, because administratively again, getting something in the *Federal Register* in the next few months, and then getting it operational by January 1st would be extremely much more difficult if we have various options at hand.

DR. LAZARUS: I think to pick one of these bundles without understanding what the quality outcomes are going to be is very difficult. I really think you're going to have to discuss the outcomes before you ask us to pick one of these bundles.

CO-CHAIRMAN AUGUSTINE: Well, that was another

reason why I'm hesitant to choose a particular bundle today, but rather just to say it would be good to agree to just have one in the end. As I said earlier, all these things impact each other. After we get through the pay-for-performance and the case mix, we'll have a better idea of which bundle would be appropriate because all these impact each other. That's one reason why right now I just want to have an understanding that isn't going to be a multiple option demonstration; that we're going to come to an agreement on one. After we do some more pay-for-performance and discussion on case mix, then we will say this is the one we're going to choose.

DR. EGGERS: I have a question for Mike. You can't make a decision on which one of those four until you know what the outcomes are. What outcomes can be given to you to help you make your decision? What outcome are you looking for here?

DR. LAZARUS: Well, I mean, I don't know what other is out there. I'm still not sure what other is.

DR. EGGERS: About $16.

DR. LAZARUS: I understand $16. I'm not going to vote on 1D unless I know what other is. You've got to tell

me what other is. If we're going to have albumin as an outcome, I'm going to look for something in here that's going to help me get albumin up because I don't see them in there right now.

SPEAKER: Do you know how to get albumin up?

DR. LAZARUS: No, I sure don't.

SPEAKER: Tell us, we need to know that.

DR. LAZARUS: So you've really got to tell us what it is that we've got to achieve before I can figure out whether I want the extra three drugs, seven drugs in 1C . If infection's not in here, why do I want to pay for a bunch of antibiotics? So is infection rate in or out? Is that going to be an outcome? Is it just anemia and KT over V?

MR. BACHOFER: Does that turnaround, by the way? Does it say that if you want to include infection drugs and labs in the bundle, that you should have a quality measure or a performance measure?

SPEAKER: Yes. Oh, yeah.

(Chorus of yes's)

CO-CHAIRMAN AUGUSTINE: Mike, you're helping make my point. I like when I state things, and people then turn

around and make me look smarter.

Let me get back to my point. We are going to talk about this in much more detail with the pay-for-performance discussion, with will occur after a break which we're going to take in just a minute. But I would like to garner and understanding that we would go with one option as opposed to more than one. I want us to kind of be in agreement on that. I don't think more than one is an option that we're going to be able to administer in time to meet our statutory requirements.

Any opposed to going with just one option?

DR. WISH: Not at all. What I was going to say is for 88 bucks a month, which is the difference between 1A and 1D, you're going to have a lot more burden, in terms of performance measures, to look at all those other things that you're including for basically less than 3 percent of the total cost. So I'm just wondering whether it's worth it; that's the issue. The administrative burden of developing all the payment-for-performance measures and the data collection, everything, for the 88 bucks a month that you're including in the bundle I'm not sure is worth it for CMS.

CO-CHAIRMAN AUGUSTINE: There's the payment perspective and then there's the quality perspective. We're going to talk about this more this afternoon. That's a good segue.

From my understanding, based on the nods at the table, we're going to move down the path of having one particular bundle, which we will discuss at further length after our pay-for-performance and potentially even some further feedback from our contractor later today. With that said, we're going to adjourn for a break. Let's reconvene at 3:05.

(Whereupon, there was a brief recess.)

CO-CHAIRMAN AUGUSTINE: One of the things I'd like to do before we start really honing down on a particular bundle is I'd like to have the presentation on pay-for-performance occur. After that, we're going to carve out some time. Henry's only going to take about 30 minutes for us to discuss and start debating particular bundles in a little more detail.

Henry, if you could go ahead and do the pay-for-performance piece, we'll go from there.

MR. BACHOFER: Okay. The purpose of this

presentation is just to sort of help frame some of the questions that need to be addressed if we are to include a pay-for-performance component of the demonstration. Pay-for-performance, as you probably are aware, is a major priority for the administrator of CMS today, who is very interested in promoting that. It is our belief that it will be desirable to create or construct some kind of pay-for-performance element of this demonstration. In addition, as we've been discussing up to this point in time, there are a number of issues that appear to be conducive, if you will, or goals that could be pursued perhaps through a pay-for-performance component rather than trying to do it strictly through the sort of mechanism of bundling services into the payment mechanism.

So my purpose today is really to begin laying out the sort of questions, issues, that will be on the table to provide s some guidance as we go out of this meeting and begin structuring an actual solicitation that we would come back to a structure for what the demo would look like in the next meeting. I would urge people not to expect that I am going to unveil a magic set of the perfect criteria or goals that would go into a pay-for-performance thing, but I

will touch on what some possible quality measures might be, but only in the most rudimentary terms.

First of all, just a point of orientation. The purpose of pay-for-performance and quality incentives is a fundamental break really with traditional thinking. The characterization that I would give to it is that the goal of P4P is to allow outcome, what is done for a patient, to begin to influence payment to the facility rather than having payment to the facility or provider be determined entirely by what is done to the patient. It's a little bit too neat perhaps a formulation but I think useful one.

CMS has generally defined the goal of its own P4P strategy, which is still evolving -- it's very much a work in progress -- as promoting the right care for the right patient every time. And following the lead of IOM, we have adopted generally the same framework that they adopted in the quality chasm approach for thinking about the kinds of measures that we might include; what are measures of safety, effectiveness, patient centeredness, timeliness, efficiency and equitability. Basically, those are also the kinds of things we would like to promote as progress along each of those dimensions.

What is the relationship between P4P and bundled payment? We've already seen sort of an issue that has a lot of different components, a lot of dimensions, it's very large, and it's very complex. A significant question in my mind is in a sense, are we talking about grafting a P4P component onto the bundled payment demo, or are we talking about sort of using P4P as an integral part of that bundled payment demo to sort of support the overall or the same or similar objectives that the bundled payment has? I think in some ways the notion of bundled payment can be seen as a kind of P4P. It's an attempt to create incentives for those providers who are more efficiently able to meet the needs of their patients for service, which is one of the primary goals that I think a P4P system would have. It's promoting efficiency, effectiveness, timeliness of care, and so on. And to the extent that improvements along those dimensions result in lower costs for the facility, then by virtue of having a fixed-payment amount, they are in effect being rewarded for those efforts. That essentially a kind of P4P notion that is inherent in the basic notion of bundled payment, or prospective payment, more generally.

In general, it is kind of a matter of

perspective. The questions that we'll be really looking at are how can P4P support the bundled payment demonstration either by dealing with issues that bundled payment, as we've defined it, do not address, or by dealing with issues that bundled payment may create?

That's so much for certainly a policy perspective on it. At a technical level, there are about six questions that you inevitably run into on this that need to be address in designing a P4P system. The first of those is simply what are the P4P incentives for. We've already had some discussion of that. Are you paying for management of infection, are you paying for management of vascular access? What exactly is it that you're trying to pay for through these P4P incentives?

How should the P4P incentives be funded? Where does the money come from to pay for it? Generally, P4P incentives come out of some kind of savings that are projected due to increased efficiency, but we can come back to that, and we'll discuss that in a little more depth in a minute. There's a specific technical question about very well and good in theory, but where does it come from when we actually try to come up with the money to write the

checks against.

Thirdly, how large do the P4P incentives need to be? Is moving 5 percent of the money around enough? Is moving 1 percent of the money around enough? Do you have to be moving more than that? Specifically, an important question is, well, how big are the efforts, how much effort, and what is the cost of the effort to achieve those performance objectives? What does that cost look like and how does that relate to the amount of money that's put on the table in the form of the incentive payment? Asking someone to achieve and improve in quality that might cost $10 per patient per month and offering to pay them $5 per patient per month is scarcely and incentive for them to do it. That's the sort of notion there.

Fourthly, how should the P4P incentive be earned? What is it that you have to do in order to earn it? I'll come back and talk about that in a little more depth. Fifth, what performance measures will be used? Again, we've touched on that and we'll round it out and then come back to that. And finally, whose performance is going to be measured? Is it the performance of the facility or is it some larger group?

MR. CANTOR: How will the components be measured?

MR. BACHOFER: That sort of cuts across a number of issues; how is the P4P incentive payment earned and what performance measures are you going to use for P4P? I think you'll see how those two dimensions interact with one another in a second.

The first question then is, what are the P4P incentives for? One approach or one way of thinking about this is to say, well, what we want to do is use P4P to support the bundled payment itself, the purposes of the bundled payment demonstration.

PPS creates incentives to improve efficiency. P4P in contrast creates explicit incentives to improve quality. So the question is, can we use some of those measures to support, if you will, the overall purposes of bundled payment, which was to create more effective and more efficient meeting of the needs of dialysis patients. Measures that you might include in this area would be measures of adequacy of renal replacement therapy, effective management of comorbidities and so on.

On the other hand, you could also reach beyond the bundle of services that are included for P4P and not

just look at the question of how well are you dialyzing patients and so on or how effectively, but to say we want to touch on other issues that may in a causal way contribute to that, but that are somewhat more loosely connected with the underlying purposes, if you will, of the resources that are being paid for through P4P. Those might include management of vascular access, coordinating care for underlying diseases, encouraging appropriate modalities as we just talked about in this last section and the choice between PD and HD; how could we use the P4P component to do that; is that something that comes explicitly through a bundled payment, or how do you even perhaps encourage appropriate use of inpatient care? So there are various questions there as to the payment incentives that we're trying to construct here, what purposes are those related to.

I think the tail end of the last discussion, I think, Dr. Lazarus, you were saying, what are the quality incentives I have, and that will sort of drive what's in the bundle and my question of, well, what's in the bundle, and that might drive what quality incentives I would want to put in, are two ways of asking the same question, two

different perspectives on that. But the underlying question is what are the incentives really to be used for in some sense.

Secondly, how will they be funded? There are, as I indicated, in any prospective payment system, implicit efficiency incentives. If you can be more efficient in your use of EPO, if you can be more efficient in your ordering of lab tests, you will benefit from that, so there are implicit incentives in having a fixed-price payment system for that.

There also are implicitly incentives for increasing effectiveness, provided the increase in effectiveness is cost effective; does it increase your cost by more than the amount of payment you have? There are incentives for better management of complications in comorbidity as both part of managing efficiency and effectiveness and other dimensions that are mentioned in the IOM report; safety, timeliness, patient centeredness, and so on.

All of those improvements, if you will, in quality are things that could be viewed as implicitly funded out of savings that a dialysis facility is able to

achieve, given the bundled payment amount, or the difference between what it cost them to provide those bundled payment services and what they're actually being paid.

However, it is also possible to create explicit quality improvement incentives. That would require additional funding of some sort. There are two basic ways of thinking about where that additional funding might come from. One is external savings, if you will. Well, obviously there's three actually. One is that you appropriate more money and put that on the table. In this demonstration context, Congress has not really appropriated any additional money to be put on the table for P4P components of a bundled payment demo, so that one is somewhat off the table, I think, at this point.

Secondly, you could look for external savings. What I mean by that is that if through the better management of the care that the patient has and given the incentives that are created, you might realize savings on services that are not paid for through the bundled payment. The best example of that, the clearest and most obvious, is vascular access.

If by moving towards increased reliance on fistula you can reduce the incidence of hospitalization, if you get improvements in quality of care, fewer days per thousand or whatever, there may be additional money that would be arguably available to fund P4P incentives that would be really what would cover the costs of doing those things to increase the reliance on fistula or whatever it is that your targeted quality improvement would be.

The third approach -- I put these in this order obviously for a reason, for most desirable to least desirable -- is a conventional approach. If you look at many P4P programs around the country -- particularly here I'm thinking about the California demonstration with the Californian physicians -- is through a withhold, a set aside, some removable of funds and then disbursement of those funds based upon achievement of the quality targets. That is of course also the way in which the P4P component of the capitated ESRD disease management is being funded, is through a withhold arrangement. Any of these are things that we would need to think about as we go forward.

Secondly, how large would the incentives be? The purpose of the incentive payment can be conceived of as

two ways. It can be seen as a source of operating revenues, if you will. It's payment for doing the things that we want you to do in order to achieve the improvements in quality that we are hoping that you will achieve, or it can be thought of as simply a bonus for an investment in improved service. You may be earning the bonus payment, but it's not intended to fully compensate you for doing these other pieces.

The considerations that would involve sort of a choice along this dimension are what is the cost of improving quality and is that cost something that is recoverable, if you will, through the implicit incentives of the bundled payment demo, through the things that you would be doing within the bundled payment demo, or is there a need to sort of look beyond simply your ability to generate those savings out of the bundle and do things in addition to or extraneous to that that would require additional funding? In any case, the real question here is to look at what it is the cost of accomplishing the improvement in quality would be, and then how much money has to be put on the table to either motivate people to pursue that improvement or enable people to pursue that

improvement by providing sufficient revenue.

There are a variety of ways of how do you earn P4P incentives; basically four. Generic approaches could be adopted, a absolute consensus-based standard. Some of the KDOQI (phonetic) guidelines would fit under this heading. We expect to see certain threshold values that are actually achieved. You could have a competitive standard based upon a norm for a group of providers. Generally that has been used. You could have an improvement standard, not so much what are you doing relative to an absolute standard, but what is your improvement over your own performance over the past. And finally you could combine these in endlessly creative and convoluted ways, as we've seen out of a number of P4P demos around the country in both the public sector and the private sector. In fact, again, the capitated ESRD disease management demo does use a combination of both an absolute standard and an improvement standard within it. So we're trying to encourage people to improve their performance, but also to meet some absolute threshold.

What sort of quality measures might be used? Tom, I think that is one part of the answer to your

question; how do you go about measuring quality or performance? One is through improvement and one is against the specific standard.

What specific measures might you use? This is of course an enormous area. Again, as I said, I would love to think that I had a magic box here that we could reach into and pull out the specific standards. The good news for us is that because of the amount of work that has gone on in the ESRD community, there are a lot of standards out there. Whether those are suitable for adaptation or for use here would be something that we would be looking to people around this table to advise us on.

There are a number of possible measures that have certainly frequently been posed or noted; adequacy of therapy, the incidence of complications in comorbidity issues around use of vascular access, the extent to which you have affected the management of anemia, modality choice itself could potentially be some kind of a quality measure that you would want to adopt and so on and so forth.

I think this is where the discussion perhaps should focus on what kinds of measures might people propose that we include. And when we come back to you, if we go

down the path of a P4P component -- which I believe we will obviously -- what kind of measures should we be looking at or including in there. One part of that might be to think a little bit about what kind of criteria would guide the selection of those measures or which measures you would include in the package.

Along that dimension, MEDPAC, in its recent comments on pay-for-performance, has sort of identified some basic performance measures. I don't want to speak for MEDPAC. I know we will have an effective presentation if I've got this wrong. But essentially in their most recent report, I think MEDPAC identified four broad criteria; the use of acceptable evidence-based measures. In other words, whatever measures it is that you use have to be acceptable to the industry or the professions of the people whose performance you're measuring.

You have to be able to collect those without an undue burden on the provider or on the Medicare program for that matter. There has to be an acceptance of risk-adjusted methods. If there is a belief that these measures have to be risk adjusted and that there are specific ways of risk adjusting them, then your measurement

should use those accepted risk-adjustment measures.

Finally, there should be a possibility of improvement along each of the dimensions. You don't want to pick simply measures that people are already doing well on. They should apply across a broad range of care. The performance should be under the provider's control, not under the extraneous events, which is really part of risk adjustment. And it should focus on those areas that are most in need of improvement.

With that as a very quick sort of overview of the kinds of dimensions that we would need, the question then I think comes down to. One is, what is the role of pay-for-performance within the demo, how might it be used, and, specifically, what kind of measures and methods of measuring performance might we want to be incorporating into whatever P4P proposal we come back to you with at our next meeting?

CO-CHAIRMAN AUGUSTINE: Thank you, Henry. Actually, that was a wonderful segue. As I stated earlier, we kind of took a quick break to listen to P4P, and now I'd like to kind of get back to us talking about --

CO-CHAIRMAN RUBIN: Before we do that, what do we

need from either the staff or does the staff need from us in terms of instruction to get our arms around this P4P? We have, in the course of the previous discussion, placed what I think is a very large burden on the P4P mechanism to make this thing fly. Henry has raised all of the right issues in his paper, so somehow we've got to figure out how it's going to be funded, how much money it is, and the answers to some of the other questions.

I guess my question to either the group or to staff is, what are the next steps? As you pointed out, we need to get this done. We're going to have two days together in July and I expect that we would say a P4P proposal at that point in time. I just want to make sure that everybody has the information that they need to do that.

MR. BACHOFER: If I could actually start to respond to that as I think about what we all have to do to get ready for that next meeting or to draft something. At potentially the risk of doing some violence to the complexity of the issue, there's sort of two questions that I think I have. One is sort of a very mundane question and the other is sort of a bigger picture policy question.

The more mundane question is, where does the money come from to pay for this? If there's going to be a P4P component of this, how should it be funded? If you look at the three options over here of additional funding, external savings and withhold amounts, essentially it would be useful to hear some discussion from people as to what the relative acceptability of those various methods are.

If we're talking about bundled payment but withholding a significant amount of it, is that something that sort of says, no, we're not interested right up front, or is there some interest in the possibility of using some element of a withhold arrangement to help pay for or fund P4P incentives, or are we looking at simply trying to make the best case we can to then seek additional external funding for this?

As you know, there is also of course the proverbial 1. whatever it was percent that was provided in this, but it is not our understanding at this point that that was intended to be use necessarily for P4P, and in effect that becomes a kind of a withhold if you were to turn to that. So there's a variety of questions that are simply related to this sort of the question of where the

money comes from.

CO-CHAIRMAN RUBIN: Just to throw in another wrinkle, Jay Wish earlier today talked about the difference between process measures and outcome measures.

MR. BACHOFER: Right.

CO-CHAIRMAN RUBIN: One might argue that to do one, you have to make a certain kind of investment, and that the fruits of those investments might be the outcomes. So it's possible that there might need to be additional funding for X and funding out a savings for the other type. I guess what I'm saying is, we need intellectually to move this forward in a time frame that I think makes sense. Before we all depart this afternoon, I'd like to have some understanding of what the committee can expect.

MR. BACHOFER: That actually gets me to the second question, the bigger question. I have heard a fair amount of positive, favorable discussions of P4P notions around the table from the members of the committee. The question that I would pose back is simply, what is it that you would hope or would want a P4P component on this demonstration to accomplish? What is it that it can contribute to the demonstration of this larger bundled

payment? That's a little abstract. But in a sense if we could leave this room with an idea of, oh, okay; what people want is something that would be working. Whether that's specific measures or types of -- I'm not entirely sure at this point it's easy to hammer on vascular access.

CO-CHAIRMAN AUGUSTINE: Real quick I guess to expound on something I said earlier, the role that P4P plays here, if all we have to guard against unutilization in an expanded bundled environment is the conditions, then you could very easily see patient care kind of regress to the means, so to speak the words, "patients hemoglobins are between right and 11." Not to say people would provide that care across the board, but there would be an incentive to do so financially. The P4P would add an additional kind of balance to unutilization to not just say that the minimum is acceptable to us, but that we would like to provide additional monies to those and recognize those that provide the highest quality care. So it's an issue regarding its unutilization and a recognition that people are doing the best they can for patients.

One of the issues here is really trying to get the payment system centered back on our beneficiaries. As

of right now, because of the payment system that we administer, the incentive is to maximize separately billables; it is not tied to patient outcomes. As a payor we need to change that, and that's why we're here and why we're working with you to try to figure out how to do that.

MR. CANTOR: I feel that if we start at the end with payment, or what's the beginning of payment, the amount of money, then we're not going to get traction. It seems to me like the plastic's too soft here. By principle, it sounds wonderful; pay-for-performance. Every child should live in a happy home. It sounds great. But I think we approach it from the standpoint of what are the exact performances and ask two questions. First, if it influenceable by the provider, and second, how important is it because by its importance we can, in terms of the money, influence whether it's going to be a necessity. In other words, a facility has to have this extra money, so they have to achieve this, or if it's going to be something along the lines of a bonus.

But all those things only come out as you get agreements on what are these exact performances, just like we just covered vascular access. Otherwise, I think that's

what's happening in this room is that when we say pay-for-performance, I have a feeling that everybody has in their mind maybe a separate performance issue, which leads them to take a position to either agree or disagree already in their mind. That's why I was thinking that we could get traction -- maybe, it's a suggestion -- by head on address what are these performance issues, and then maybe it will become clear for us as to how we proceed.

CO-CHAIRMAN RUBIN: I agree with that. What I'm asking the staff is I don't want to be sitting here six weeks from now and say, well, remember Tom Cantor said we needed performance measures? Where are they? I want to be very clear in our instructions that we need to see a plan, and it may well be a matrix. It may be a bunch of performance criteria, a bunch of funding criteria, and a bunch of how you earn it criteria. And then we can sink our teeth into something in a substantive kind of way.

CO-CHAIRMAN AUGUSTINE: We've got a good starting point with Jay and all the work that CMS and Dr. Owen and others have done with the CPMs. We've got a good starting point for performance measures.

How they fit into the demo -- for example, in the

disease management demonstration we're actually capturing the CPMs on a quarterly basis and making payments, from my understanding, on a quarterly basis. That way they're more timely, more actionable, and have a larger impact on practice patterns. Recommendations and considerations such as that would be helpful for us to have.

DR. LAZARUS: Two major things in all of your plans, 1A through 1B, is the composite rate dialysis. The major measure there is adequacy, so that seems to be a slam dunk. The other is EPO, and the measure there is hemoglobin. So it seems to me you have two measures that you're going to have to put out. My only concern about those two measures is that I think we're at the -- we're not going to get any better. If we can stay where we are, terrific. So if it's acceptable to have an outcome where you can maintain where you are, I would suggest that adequacy of hemoglobin are two that you have to put into this, regardless of the plan we take.

CO-CHAIRMAN AUGUSTINE: They'll need to be in there, but they're not as much an opportunity --

DR. LAZARUS: But your concern is that we're going to gaming the system and drop off on both of those.

So I think they have to be there to make CMS happy that the participants are not gaming the system.

CO-CHAIRMAN AUGUSTINE: Agreed. They are a minimum; they are a starting point.

MS. GREENSPAN: If you made it so they were just required in order to get your gain from the others but you can't go back in those two, so that the gain, you'd list your other criterion for a gain, and then say, but you only get those if you didn't go back.

CO-CHAIRMAN AUGUSTINE: One of the things I really would not like to neglect is minimum metabolism because from my understanding -- that's an understanding of how much that's a killer. It's harder to manage from my understanding. But that's something that you could weigh a lot better than I can.

DR. OWEN: Somebody's got to be gadfly here. I want to return to Jay's comment earlier about process measures versus outcome measures. First of all, I'm reminded, what do we with renal replacement therapy when we dialyze someone? We're doing chronic life support. There are other components of health care where they actually use outcome measures, which is to say they look at mortality.

I mean, all this stuff we're doing in terms of dialysis dose, hemoglobin, et cetera, I mean, we're talking about cost but we're dancing around what is a real issue here. And that is we've got an awful mortality rate.

What has IDOP shown us? There is something that is being done around the world that is influencing mortality rate. So I'm going to be a real provocateur, throw a glove down, and say why don't we reward somebody for driving the mortality rate down? And I'm aware of the issue of adverse patient selection, but at the end of the day it's just like cardiac surgery. And that is who comes out, and who's alive, and who's dead.

CO-CHAIRMAN AUGUSTINE: As a payor -- because I'm purchasing care basically on our beneficiaries' health -- we're interested in outcomes. We want to make sure our beneficiaries receive the best care possible, and that's our self-interest. As providers and as practitioners, you control the process. We don't want to really dictate process; our interest is really in outcomes and leave it to you to figure out how to get the best outcomes.

So to be fair to practitioners, we would need

some consideration for process indicators because that's what they control, but there needs to be some consideration for outcomes as well. And hopefully you choose processes that are highly correlated with outcomes. Especially with mortality, some ESDR are more highly predictive than others. So some understanding of structure, process and outcomes, all three of them may need to be considered for this pay-for-performance.

DR. BURKART: One thing that we might look at, I believe there's a paper about to be published that has looked at what percentage of your patients meet all of the criteria, and that outcome is related to meeting three out of the five or four out of the five; not do 85 percent of your patients have a hemoglobin above 11, but do 85 percent of your patients meet five of these CPM indicators and that actually survival is related to meet the number of those indicators. That is something we could consider looking at if in fact that data is true and is published.

DR. WISH: I don't disagree completely about the importance of outcome measures, but I think until we get a handle on adverse selection and cherry-picking, I think we still have to go more towards process measures for the time

being because these are more clearly actionable. That's clearly what the hospitals did, and I think it's working in the hospitals. Almost all measures that the hospitals have to report are process measures; did they treat the MI with a beta blocker, did they treat the CHF with an ace inhibitor, did they treat the patient with pneumonia within four hours of the diagnosis? These are all process measures, and the hospitals are paying attention and they're working. I think the same thing can happen in ESRD.

DR. OWEN: This group looks at hospital-based mortality. They get rid of all that other crap. The 100,000 lives campaign is mortality. And there's a certain amount of hubris that comes with I know what are the 8 or 10 things that you should focus upon. You don't know that. We aggregate them and what do we have? Fifteen percent of the variability in mortality. So how do I know my four are necessarily better than your four?

Quite candidly, I'd say let the practitioner decide what are the four, or five, or whatever, that are important. At the end of the day as corny as it sounds, I really do think it comes down to who's alive and who's dead

in that unit. I can drop the mortality in there, pat you on the back, and then I'll come in afterwards and try to learn what you do.

DR. WISH: But we have guidelines; these aren't arbitrary. I mean, we have cardiovascular guidelines in DOQI that say you've got to look at the lipids and you've got to treat them with statins, and you've got to treat the hypertension.

DR. OWEN: And show me that those have reduced mortality. That's an expert panel that set around and made, as you know, a plethora of assumptions. The data's not there to support that those have changed mortality. The ones that we do have mortality data on, we're sitting here saying, geez, we don't like 8 percent; it's too low in terms of accounting for the variability. I aggregate the ones that we've patted ourselves on the back on, and the best I can get is 16 percent.

So there's something out there, the preponderance of stuff that is out there, that is influencing mortality we're not smart enough to pick up on. Maybe use this truly as an alpha test to try to find out what there is because there are differences in mortality.

DR. WISH: Well, if you're going to just look at mortality, who's going to take the patients that are half dead when they get to your door, the patients with HIV, the patients with severe cardiovascular disease?

DR. OWEN: Show me that that has occurred. We talk about it and we talk about it. I remember in the RPA we sat up there and said it was occurring, and then asked for the data and couldn't find it.

DR. WISH: It's not happening yet because we're not being paid for it.

MS. GREENSPAN: But also just the interval it takes to reward the accomplishment of the outcome, it takes too long to get the mortality to be able to see it because there's too much intermittent that makes your risk very high.

DR. OWEN: Fifty percent of my mortality for an incident patient occurs at 30 months. That's pretty fast.

MS. GREENSPAN: But if you're going to do quarterly rewards, the change in the departure from the expected mortality to the actual mortality rate, how can you do that so quick?

DR. OWEN: I didn't know we had decided on a

frequency reward.

MS. GREENSPAN: I mean, you're talking about something like that. If you are not talking about doing a three-year reward, how are you going to do that?

SPEAKER: Rate of infection. Is that less controversial? Is that more influenceable by the provider?

CO-CHAIRMAN AUGUSTINE: I think we've heard already kind of some general consensus that infection rate is definitely something we need to keep track of. I don't think we've decided any particular aspects of the pay-for-performance, but infection would definitely be up there with any others, as we start hauling it down.

Other comments on P4P?

DR. LAZARUS: I want to address the funding mechanisms. Is that not part of the P4P?

CO-CHAIRMAN AUGUSTINE: No. Jay, one of the reasons why outcomes are very important is because outcomes are measurable financially. For example, hospitalizations. If there's any chance that there's going to be a payment above and beyond, which is an uphill battle to begin with OMB, there would have to be a case made that better access management reduces hospitalizations.

I do know that ASN brought this up to the administrator last week and we had a discussion. He is not adverse to considering the shifting of money between A and B. It's not something that's exactly a barrier as has been made out in the past, but there has to be a good case, a good business case made. What would be helpful is to have outcomes like hospitalization included in your P4Ps. You know that the savings in Part A are at least paying for any additional bonuses on the Part B side.

DR. WISH: I'm not saying you can't measure it; in fact, you should measure it. I'm not saying you can't report it, and you should report it. But I'm just saying in your initial round of selection of criteria for P4P, I think you should be more weighted towards process measures because you're going to get buy in. This is stuff that's actionable. This is stuff that can be done at the facility level and the provider level. People can put their arms around it and say, yes, I can do that. You tell them I want you to reduce mortality, and they're going to say, I can't do that.

CO-CHAIRMAN AUGUSTINE: Well, most measures we have out there are process measures, like from the National

Kidney Foundation, KDOQI. They're mostly process measures. For every four or five process measures, you're going to need a mortality, you're going to need a caps instrument. You're going to need something that's more outcomes patient centered, but I think there's a good balance that can be found between those, that if you have a good P4P system.

Other comments on P4P?

DR. LAZARUS: The three choices we had was external choices, which Brady just addressed, which I think is the only option, because withhold to me is not a tolerable choice. If we have 500 facilities in this demonstration, half of them are going to have improved results and half are not. The half that are not are going to fund the other half with a withhold, which means the bad clinics, the poor clinics, are going to get less reimbursement, and I don't see that as a viable way to improve. You can't take the poor facilities and take the money to pay the good facilities. I don't see that as a workable solution.

CO-CHAIRMAN AUGUSTINE: I agree with your point, but I will also add, that’s assuming there is no efficiencies driven into the system.

DR. LAZARUS: There are no efficiencies that we can do with any of these things that I see that will reduce my cost. I'm going to reduce cost of hospitalization. I challenge anybody around this table to tell me where a dialysis unit is going to save money with implementing any of these things, except for reduced hospitalization. We're not going to create any efficiencies in the units, I don't think.

MR. BACHOFER: I think this is within the congressional mandate. The expectation that there can be increased efficiency in the use of injectable drugs is more of a -- than anything else.

DR. LAZARUS: Well, I mean, given more EPO, explain to me where the dialysis unit benefits from giving more EPO --

MR. BACHOFER: Not giving more, giving less. In other words, the savings that they would achieve would be increased efficiency in the use of these inputs.

DR. LAZARUS: Well, if the goal is 80 percent of people with a hemoglobin above 11 -- and we're all there, struggling working to get there -- I assume most people give adequate iron, or the physicians that are willing to

give iron, give iron. With a reduction in EPO dose, more efficiency is going to drop that percentage of patients down below 11, so back to the goal of -- I don't see a lot of efficiencies here.

CO-CHAIRMAN AUGUSTINE: I wouldn't say that more work less, and I wouldn't single out Epogen. I think that it's more than the fee-for-service environment. There is an incentive there on the side of caution that potentially provide too much. We don't know how much and we believe there may be some savings for more efficient use.

DR. LAZARUS: If you look at the distribution -- I hate to beat this to death -- the distribution gets 80 percent of the people above 11. That largest percentage of people that looks to be too high is a normal, physiologic distribution that's not going to go away. I don't care what you do; that's not going to go away. If you want 80 percent of the people to be above 11, you're going to have 30 percent of the people above 13. I don't care what you do; you can't change that. That's not going to change. If you give me that bottom goal, look to the distribution to tell you where everybody else is going to be.

CO-CHAIRMAN AUGUSTINE: I don't disagree with the distribution. You and I have had this discussion, and I think it's pretty well known from almost everyone on this board. I think one of the concerns is, for those patients that are very low and stay very low -- that are getting significant amounts of separately billable -- there may be different care practices that will provide the same outcomes with a lot lower costs.

DR. LAZARUS: We're back to transfusions, and is that an acceptable practice in this demonstration. If I get to 90,000 units of EPO for a week in a patient, that it would be good medical practice for me to give them a transfusion rather than more EPO. If this demonstration's going to say that, then that's an opportunity. But there are a lot of people out there that are going to argue and look down on this demonstration if we do that.

CO-CHAIRMAN AUGUSTINE: I think that's a clinical decision to make. I do think, including the blood components into a bundle -- if we're going to include anemia management or EPO, we need to include the blood components in there as well.

Other comments?

DR. BURKART: When we're coming up with whatever the measurements are going to be, is there a way that we can get around the following problem? For instance, if we pick, as a process measure or an outcome, a percentage of patients at a certain level -- and some units are already there and some units are not -- the ones that are not can improve and can get there; the ones that are already there can't. Is there something that we can pick that's apropos for all units or do we have to pick different things depending on the unit's starting point?

CO-CHAIRMAN AUGUSTINE: You say that MEDPAC has actually provided some sound leadership here. Personally I would like there to be an incentive to improve the care for every patient, not only facilities that can reach a benchmark, but also for those facilities who have a large opportunity for improvement. In our previous disease management demonstration, we paid not only for attainment of thresholds but for percent improvement. That's something I think this board should evaluate and consider for this demonstration as well because that gives every facility an incentive to improve.

Let's move back to the actual bundle composition.

I want the P4Ps to roll around a little bit, and we're going to talk about that again. But first off, I'd like to get back to the actual bundle composition.

One thing Dr. Wish stated earlier is that if we get most of the way with 1A from a financial standpoint, is it easier for CMS to go with 1A? From a financial standpoint, yes, but one of the things that's good about a bundle is it's easier for us to administer. For example, 1D actually gets rid of the 50/50 rule. The 50/50 rule is a big pain for just about everyone, and it's very difficult to administer. There are trade offs here between 1A and 1D.

After the last meeting, when Dr. Lazarus said other practitioners send the patients in here to get blood draws from the facility, that started making me think about vascular access. I know we talked about this earlier. Personally, as long as they're professionally competent to draw blood in the facilities, which I believe they are better than just about any other place, I would like the blood draws for other outpatient facilities to be done in a dialysis facility. I would like all the labs to be done there. Number one, you will know who's sticking your

patients' arms, and, number two, have a better ability to manage the access. I don't have a problem with that, and that moves towards 1D as well.

DR. WISH: No, that moves towards a smaller bundle.

CO-CHAIRMAN AUGUSTINE: Well, that would include all outpatient labs.

DR. WISH: I want all these tests that everybody else wants.

CO-CHAIRMAN AUGUSTINE: That would be 1D. That would include all labs. All labs would come through the bundled payment to the facility.

DR. WISH: Right. But then you're putting the dialysis unit at risk financially for all these other tests that everybody else wants. I think that's an disincentive for 1D.

CO-CHAIRMAN AUGUSTINE: We want the patient to be managed better. Right now, the patient shouldn't really be getting blood drawn at a lot of different facilities anyway. There should be kind of an understood message.

DR. WISH: Right, but there's a financial disincentive for the dialysis units who accept all these

blood draws if they're not getting paid for it.

CO-CHAIRMAN AUGUSTINE: Those monies or those other outpatient settings could be put into the bundle so that facilities are getting paid for those other outpatient labs, which are included in these analyses. So they're getting paid for those labs, and their job would be to kind of coordinate and ensure that patients get their blood drawn from the facility and not get it done from other locations because they could be liable for those costs if they occur in another outpatient facility or location.

MS. CUELLAR: You're talking about blood draws versus the lab --

CO-CHAIRMAN AUGUSTINE: Excuse me; the test, the actual test.

MS. CUELLAR: Right. But then who's responsible for that test? Is it the facility and the physician that's in the unit then responsible for the results of that test?

CO-CHAIRMAN AUGUSTINE: If it's in the bundle, the actual payment for the test would be in the expanded bundle.

MS. CUELLAR: But there's a difference between who's sticking the arm and who's monitoring that lab

result.

CO-CHAIRMAN AUGUSTINE: Who's sticking the arm, who's running the test, and who's monitoring the result? In the situation Mike described, it it's done before another practitioner who's not credentialed at the facility, they write a script and they come into the facility, and the blood's drawn. It goes to the facility's lab, is returned, and they would send the consult back to the originating doctor.

MS. CUELLAR: So who tells the patient the results in that scenario?

CO-CHAIRMAN AUGUSTINE: Excuse me?

MS. CUELLAR: Who gives the patient the results in that scenario?

CO-CHAIRMAN AUGUSTINE: The person that ordered it I guess is the person who wanted it. They should be the one to share it with the patient.

DR. LAZARUS: That's a medical question that you're asking. Who is legally, morally responsible for a bad test that comes back? The dialysis unit has a bad test, and this doctor outside who asks for the test doesn't pick up on it. The patient has some contractible disease

and dies. I'm stretching here. But who's responsible now that it's on our table? We got paid for it; we drew it. Who's responsible for it?

CO-CHAIRMAN AUGUSTINE: When someone refers a patient and they get their blood drawn at your facility today and you run it, and you write the consult, back, that's no difference than today.

DR. WISH: If it's a separately billable test today, then you get paid for it.

CO-CHAIRMAN AUGUSTINE: It's the same situation. You're still getting paid, and you're running the test, and you're getting the result, and you're sending it back to the originating doctor. The payment issue is no different. You're still getting paid today just as you are in an expanded bundle for the same test. So there's no new issues that we don't already have.

DR. WISH: But I think that expanding the bundle to include all of those tests that come from the outside world is actually a disincentive for the dialysis unit doing it. I think if they're separately billable that's more of an incentive for the dialysis unit to want to take those patients and do those tests, not less an incentive.

CO-CHAIRMAN AUGUSTINE: Well, if they can be an efficient provider and work with their beneficiaries to be sure that they get their blood drawn at the facility during their session, it's an economic incentives because there are monies out there that are included for other practitioners; that if that goes away and the blood is drawn all at one time as opposed to being drawn at two or three places, then there's an economic incentive for a facility.

MR. BACHOFER: The economic incentive, though, Brady, actually has two sides to it. There's the incentive that the facility is operating under and then there is the incentive that other providers are operating under. And in a bundled payment system all of those other providers would have an incentive to not provide the tests themselves and instead refer to the dialysis facility, because if they submit the claim, they aren't going to get paid for it.

CO-CHAIRMAN AUGUSTINE: It's an efficiency in the sense that instead you're getting your blood drawn as fewer times as possible.

DR. WISH: Well, I don't think all those other providers own their own labs and bill for these tests.

MR. BACHOFER: I agree, but just in terms of the incentive structure, there certainly would be. If you bundle the lab work into the facilities payment, the facility has an incentive to reduce utilization of laboratory services and so not to take on the task of doing all of those tests for other entities. But if those other entities can't handle lab tests paid for, except by having it done through the facility, then they would be -- if I could use a term that I hesitate to, it's a more coercive approach because it forces the test back into the facility so that the facility has to bill it.

DR. WISH: I hope I'm not usurping everybody else's raising their hand. Just to make a counter-argument, I think what's more important is to educate all these other doctors not to stick these patients' arms. I think what's going to happen is they're going to still stick the arms because the patient's there in their office, and they send them to their local lab, and they'll send the specimen to the local lab, which then won't get paid. And they won't run the test, and the patient will have got stuck anyway.

DR. OWEN: I guess this question is directed more

toward Dr. Wish and Lazarus. I'm reminded that maybe 5 to 10 years ago you gentlemen developed a position paper for the RPA that dealt with the issue of whether or not the nephrologist was a subspecialist who triaged, or whether or not the dialytic nephrologist was kind of the primary care physician for a patient with ESRD. I'm also under the impression that the organization with strong support from the community landed on that the nephrologist was a primary care physician for a patient for ESRD.

If I look at that chart, the amount of difference in money is not a lot. I know when I multiply it out, as we talked about, it's a lot. So I'm saying, well, if I'm not spending a whole lot of difference on the money, are there substantial differences in terms of those IOM maximums that we have on the board?

So if the nephrologist is kind of the primary care physician for a person, is there a certain amount of enhanced coordination, safety and effectiveness that's offered by having everything go through you as the nephrologist with things being bundled? At the end of the day it's not a financial issue. It quite honestly is one of actually your legal accountability.

DR. LAZARUS: That was a debate back then. I was on the pro side of the physician did everything, but that's not what happens in this country today. Unfortunately, there are many nephrologists that say I take care of the dialysis and that's all I do. What happened 20 years ago in the debate is a far cry from what's really happening.

DR. OWEN: I guess I'm asking is this an opportunity for us to drive that in that direction if people think this is the right thing to do, or do you want to have fragmented care providers? I think it was you who posed the question. If that test is sent off under my name, am I accountable for it?

I can tell you guys. I have a health system that now does a lot of free care. Whether you're paid or not, if your name is attached to that test, you have both a moral and a legal obligation to follow up. So does this give me now a bully pulpit? Does it also now make me the person who can take coordinate that care because it's all crossing my desk?

DR. WISH: Well, if you look at the continuum of care from CKD on, I think one of the major barriers that we all recognize in terms of timely referral is the perception

on the part of the PCP that the nephrologist is going to steal their patient, so the last thing we want to do is legitimize that into fiscal policy.

DR. OWEN: You saying a CKD patient. I thought this was an ESRD patient we're talking about.

DR. WISH: Right, but most primary care physicians still don't want to lose their patients to the nephrologist even once they have ESRD.

DR. BURKART: We don't know if all the labs that could be drawn on a patient are being drawn. Primary care physicians can make money with ancillaries, just like the dialysis units do, and so some of them want to do their labs. We did bring up last time that the reason a lot of these things are drawn is because the patient is on dialysis, their arm is there; let's do it.

I think that we should facilitate being able to have the labs drawn at the unit because they have ready access to the blood, but I don't know that that means that it needs to be part of the composite rate. I think that it should be that the patients can have the labs drawn there and it's a separately billable thing, and if the primary care doctor orders the lab, and your unit will allow it to

be drawn under the primary care doctor's name, we've got to do it that way.

CO-CHAIRMAN AUGUSTINE: I hate to admit this, but the payment system is much more a strong driver than you may give it credit for. If it is in the payment system, it may happen for a little while, but it won't happen for long. There are not many practitioners, or businesses, or people in this world that run their business to lose money.

DR. BURKART: No, no. If they can't do it anymore, they won't. But at the moment they probably want to have some labs draw it.

CO-CHAIRMAN AUGUSTINE: It's been 10, 20 years and we have all the best interest in the world, but it's not happening. This system is broken, and just by hoping that it will get better will not make it better. We've got to start making changes structurally to the system, and until we do so -- what's the old dimming maximum; if you do the same thing 10 times and it doesn't work, the 11th time you'll get the same exact response; something like that.

DR. WISH: Albert Einstein says "the definition of insanity is doing the same thing over and over again and expecting a different result."

CO-CHAIRMAN AUGUSTINE: I love to air my misquotes to the public.

DR. LAZARUS: I get the impression that at least you, and maybe Bob, are pushing 1D. Is that my interpretation of what I'm hearing?

CO-CHAIRMAN AUGUSTINE: I'm not pushing. I'm just saying without having consideration for transfusions and the lab work -- I mean, this is an opportunity for us to try to infuse some better coordination of care. And if we just include the few drugs, then we're not going to be much different than where we are today. All of a sudden you'll se quarantine or all of a sudden you'll see other separately billables skyrocket because that's the financial incentive that the payment systems sends.

So instead of focusing on these separately billables, we're just going to focus on other separately billables. I think if we're going to move this payment system to be patient centered, then we need to forget about separately billables and start focusing on outcomes. Pay a fair rate for a fair day's work, as the old saying goes, and then try to incentivize the outcomes instead of incentivizing the processes. That's what we're trying to

get at here, and that's why I think D is helpful.

CO-CHAIRMAN RUBIN: Could I make a suggestion? I notice we're into the public comment time, and maybe to facilitate this.

You asked me where I was. I don't know enough to know which I'm for because what I want to see is what we haven't yet seen. That is to say, what's the variation at the facility level. I want the people from Michigan to go back and dig into A, B, C and D, and look at what that variation is and how we can deal with that with case-mix adjustment, and see whether it makes practical sense to be more inclusive or less inclusive.

A lot of people have been throwing around, well, it's 5 bucks, and 5 bucks there, and $16 there. It begins to add up to real money. I don't want us to make a recommendation that the agency follows and then throws a party that nobody shows up to.

Right now, what I would like to see and what I'd like to hear again from the staff is whether they can do the kinds of analyses that were in each of their next-step slides on A, B, C and D, and come back in July, look at it, talk about it, and see what makes the most sense. But

right now what we saw is we've got huge variations. We have R^2s that are low. Now, whether they can be made better, who knows. Let's try to put some meat on the bones of what we've already seen.

DR. LAZARUS: But the only variation that really matters, Bob, is EPO. Everything else fails in comparison. So the variation there is EPO dose, and the rest of them vary within the clinical parameters. So why would you waste time looking at everything else but EPO? I mean, that's where the variation is.

CO-CHAIRMAN RUBIN: Well, we don't know that at the margin, I don't think.

DR. LAZARUS: What do mean?

CO-CHAIRMAN RUBIN: Well, we don't know whether the distribution of costs, among these other things, is random or non-random.

DR. LAZARUS: I don't know what you mean.

CO-CHAIRMAN RUBIN: Are they all centered in certain kinds of facilities, is the concentration uniformly distributed, are there some characteristics that can more adequately predict high costs in particular months? I don't know that.

DR. LAZARUS: Yeah, the antibiotics are all related to catheters. That's the other answer.

MS. GREENSPAN: One worrisome thing about 1D -- at least we know what's in 1A, 1B, 1C and if we agree that, okay, we're willing to buy that risk. 1D could have something that's an item in little use now that will become in much greater use. So for 16 bucks you take a huge amount of risk over 1C.

CO-CHAIRMAN AUGUSTINE: Do you expect certain med surg supplies to all of a sudden grow geometrically?

MS. GREENSPAN: No, I don't think it was only med surg supplies. That's what I mean. I think I'd want to see everything that we're actually saying this is now incorporated in that 16 bucks.

CO-CHAIRMAN AUGUSTINE: Well, blood would grow in one area and EPO would go down in another area.

MS. GREENSPAN: It's risky.

MS. RAY: What is added in 1D that's not in 1C? Is it just the med surg supplies?

MR. BACHOFER: Medical surgical supplies is the largest item, followed by blood processing and storage, followed by preventive services, which is about $1 million

a year aggregate, followed by blood products and blood, followed by radiology, diagnostic, EKG, ECG, cardiology, respiratory services, clinic services, CT scanning, other imaging, treatment, observation, nuclear medicine, ambulatory surgery, MRI, OR, ER, pulmonary function. I mean, many of these things are -- but they're tiny dollar amounts.

Having said that, gone down that huge, long list --

DR. BURKART: The things that are listed on page 12, 13, 14, 15, 16, 17, 18, right?

MR. BACHOFER: Right. I think we included that.

MS. GREENSPAN: But you don't want to take the risk for all those things for $16 a month.

MR. BACHOFER: No, no, no. I would argue, looking at this list, that if you go down it, what you really see is that there are many things on here that you wouldn't really probably want to bundle. Clearly, like most of the imaging, for example, was probably patients who are being referred to a hospital in all likelihood, because most of these costs, incidentally, are in hospital-based facilities. What that looks like is that the hospital-

based facility happens to have an ESRD patient that shows up for imaging or whatever, and when they cut the bill at the end of the month, they simply cut a 72X claim, even though they weren't necessarily doing dialysis on the patient, and submitting the claim, and so it comes through on this.

My contention looking at this is we would have to selectively say there's maybe three, four or five big-ticket items, where there's real money attached to it. And say those are the things that we would pull out of 1D to include into it. Today we had some discussion of blood and blood products. If we have EPO bundled in it just occurred to me that then you create incentives to substitute blood for EPO. So there's a clear substitution margin that would be raised here.

So you would want to pull blood and blood products, medical surgical supplies, and maybe one or two other items off of this list. But the other things that are smaller dollar amounts, like nuclear medicine, imaging, OR, pulmonary function, emergency room and so on, those would not be candidates for being bundled.

DR. EGGERS: Particularly if you had a system

that didn't allow anybody else to bill for that.

MR. BACHOFER: Correct.

DR. EGGERS: All of a sudden you have these bizarre, weird small things cutting of access.

MR. BACHOFER: Right.

MS. RAY: It might be helpful for the panel, for at least these 1D payments, if you could provide some sort of time trend. The best of my recollection is that at least for freestanding facilities, to look at payments in 2000, 2001, 2002, 2003 to give the panel a sense of whether or not these payments have increased or decreased over time and also to give the panel a sense of -- to the best of my recollection, this really is less than 1 percent of all facility payments.

MR. BACHOFER: That's correct.

MS. RAY: But I think it would be helpful to provide that information to give some context.

MR. BACHOFER: Just a quick response to that. These numbers are for 2003, and I had requested these because the Phase 1 report that KECC did involved an earlier year, 2002 if I recall correctly. These numbers are very close in terms of their overall pattern. So just

a one-year trend is a one-year trend, but it doesn't show very much change.

MS. RAY: Right. That's what I was going to say, just for freestanding, but I haven't looked at these 1D services for hospital base, but that was the best of my recollection.

MR. BACHOFER: This for everyone.

MS. RAY: Right.

MR. BACHOFER: These are all claims.

DR. BURKART: All claims done no matter where they were ordered.

MR. BACHOFER: No, these are dollar amounts that appear on claims that are submitted by facilities, by any facility, not just hospital-based facilities.

DR. BURKART: Because Bonnie's point is, let's say you want to buy a TV and they happen to be in the grocery store. Well, you don't go to the grocery store to buy a TV; you go to wherever. And then all of a sudden if you're told, you can only buy it at the grocery store, all of a sudden it's going to go way up.

MR. BACHOFER: The list can be amended. There are some things that may not need to be on there that can

be taken off. I mean, there more of anomalies. But some of them like blood component technology, blood components and what not, they surely would need to be in there.

CO-CHAIRMAN AUGUSTINE: Are there any members of the board who'd really like to discuss some of the intermediate bundles, the 1B and 1C? It sounds like we're talking more about 1A and 1D.

MR. BACHOFER: What I would call 1A and 1C+.

DR. WISH: I understand where you're coming from in terms of trying to close every loophole. I think as long as there's the potential for separately billable items that there will be behavioral offsets that will exploit that, and I can understand why that is attractive to CMS.

My major concern again just has to do with the data collection and the reporting infrastructure that's going to be required to adequately monitor or reward, punish, or whatever you want to talk about, all those intermediate steps between 1A and 1D since they are very, very small in terms of monetary value and yet potentially very big in terms of administrative oversight.

MS. RAY: I just want to make a point. 1C includes the Hepatitis B vaccine and the flu vaccine. I

remember looking at some earlier USRDS work that suggested that the use of certain preventive services -- and I think those were included -- was actually lower among ESRD patients than among non-ESRD patients. So I think including them in the broader bundle gives us the opportunity to improve quality of care, particularly for those two items.

SPEAKER: No, you just put in performance measures for them. It's irrespective of whether or no they're in the bundle.

CO-CHAIRMAN AUGUSTINE: Because if they're in the bundle there's an incentive not to actually do them. You'd have to have a performance measure to go along with them to ensure that they occur.

MS. RAY: Well, in the bundle and measurements together.

CO-CHAIRMAN AUGUSTINE: Agreed.

DR. OWEN: I just wanted to comment that, in fact, if you look at time trend analysis for an individual patient, it actually goes down as they go from CKD to ESRD, which makes me return to my point; who's actually driving the ship.

CO-CHAIRMAN AUGUSTINE: Every different bundle that we evaluate, our contractors had to do that much more work, and I'd like to actually focus it as much as possible.

Is there a clear distinction to Bundles 1A and 1D, which is what I'm hearing, but I may not be hearing correctly, those of you who preferred 1C, 1D.

MR. BACHOFER: Brady, if I could comment while people ponder that issue.

I actually have to say, having lived with these data far too intensively over the past two weeks, I actually see relatively little analytic gain likely to come out of detailed analyses of the individual bundles. In other words, doing a comparative analyses of 1B to 1C is not likely to turn up a whole lot of useful, terribly insightful information. What we do know at this point in time about those intermediate bundles is that they do display a different pattern of utilization; that's true.

I think where we would learn something from is to look at something that would be sort of a 1C+ or whatever you want to call that, and then see what the sort of detailed questions are that Bob identified about what is

the impact across facilities, what kinds of facilities might be adversely affected, and so on. But then hold and reserve the question -- in a sense to come back to that -- of if you were to eliminate everything between 1A and 1C and just go back down to 1C, where is that injury occurring; where is the problem arising?

As Mike has indicate here, it really is EPO that's driving this whole thing, this EPO variation, in a sense. It's not just EPO; it's that set of three drugs because I don't want to pick on any one category. So if you back out everything other than that, is there still a problem with what's left. That might be a more productive avenue in terms of what we would learn from it, but to really sort of focus on the broader bundle, and then ask do we see problems there that would be fixed by moving to more narrowly-defined bundle.

CO-CHAIRMAN AUGUSTINE: That's a good suggestion. Anyone have any issues with that? Then we should follow that.

DR. WOLFE: I just wanted to give a little more context to the case-mix adjustment. I would echo Henry's comment. One of the slides we showed compared the R^2 and

our ability to explain variation between two of the bundles. There was some difference, but it wasn't all that great.

There's been quite a bit of discussion about how miserable these models are. Let me give a little bit better context. On one of our slides -- page 18 of Section G -- it shows no model compared to case-mix adjusted. The unexplained patient variation went from $48 down to $43, which just doing the numbers is about a 15 to 20 percent R^2 at the patient level. We're never going to be able to explain the month-to-month variation; that's just pure error. And that's part of this calculation of what is the hypothetical R^2 you can hope to get to.

We're not great, but we're not terrible either. It's not nearly as terrible as 7 percent if you think of explaining all the variation. But in terms of explaining the important variation from patient to patient, we're explaining close to 20 percent of the variation from patient to patient with our current case-mix model. That happens to be Bundle 1C, but it's not going to be a very different story for these other bundles. If we put in prior EPO use, we get a substantial bump up in that.

Please, don't let the case-mix number -- at least not that particular number -- make you think, well, we're never going to get there and never have any decent case-mix adjustment. I think the interesting number to look at really is the dollar unexplained variation and can you live with that, and recognize that that's going to go down. As you average cost patients at a facility, it's going to go down rapidly. So the risk that you actually see in unexplained variation from case mix, it's not negligible, but it's also not the driving issue in this question I think. I just wanted to give a little bit of context there, and sorry for all the numbers.

CO-CHAIRMAN AUGUSTINE: Thanks, Bob. That's actually quite helpful.

Now, we're going to move to our public comment section. I know that we've had a lot of people patiently waiting in the audience and would like to opine and provide some input to the board as we deliberate. I'd like to open up that opportunity now.

First of all, we've got Mr. Kenley from Aksys.

MR. KENLEY: Thank you, Brady.

My name is Rod Kenley. I'm employed by Aksys

Limited. We make an instrument for daily home hemodialysis, so it shouldn't be any surprise that we are very gratified to hear the discussion on the intent of this body to incentivize home modalities of all kinds. That certainly was our reason for supporting the expanded bundle because we feel the expanded bundle will result in expanded choices for the patient, choices that really haven't been available to these patients for a long time now.

As I heard the discussion evolve, I heard two proposals for how to incentivize home modalities, one being what I came here today expecting to hear, that there would be one rate for any way you want to do dialysis. That would incentivize those modalities that have the lowest costs. With that, if we have quality indicators and outcome measures that are more easily reached with these home modalities, that will further incentivize the use of them.

I heard an alternate proposal that maybe we should pay less for lower cost modalities. I would strongly oppose that for the following reasons. We tried that once and it didn't work.

When we put the reimbursement in place in 1973,

there were 42 percent of all patients on home hemodialysis. That rapidly eroded to the point where in 1977-1978, there was a lot of effort to reconfigure reimbursement to reincentivize home modalities, including, most particularly, home hemodialysis. There was a lot of debate that went on, including a proposition that came close to passing that would stipulate a minimum percentage of all people that should be on home dialysis.

That didn't make it into the final rule. What did make it was the maximum number of practical patients should be put on home modalities, and 75 percent reimbursement was applied to a home modality. What happened? We continued to lose home patients at a rapid rate until 1983 when the composite rate was initiated.

Dr. Rubin, you commented that you thought that was a failure for home modalities. I respectfully disagree. The growth of peritoneal dialysis throughout the 1980's could largely be attributable to that composite rate, not entirely, but certainly there's a component. In fact, I think the failure of the composite rate was the lack of an annual update, such that by the time we got to 1990, plus or minus a year or two, Medicare patients became

unprofitable, resulting in the need to make the profit on the separately billable injectables, and therefore keep the patients preferentially in the centers, rather than letting them go home. Well, now we're recognizing the fallacy of that.

I'll give you another example of why I think putting an upfront disincentive for home dialysis is the wrong way to go, and I view this reduced rate as an upfront disincentive.

We have also back in 1978 instituted a $20 increment over the composite rate for training sessions for that month or so when the home training patients are being trained. That has never been increased. At least the composite rate has been increased three or four times. Had that been increased by the rate of medical products inflation that would be $110 right now.

I went to the cost reports and looked at all the clinics that were reporting more than 100 home hemo training sessions per year. On average, they are losing $4,680 for each patient they train for home hemo. Secondly, they have to pay for the modifications to the plumbing and electricity, another $1,200 to $1,500.

They're eating $6,000 of negative cash flow to get a patient at home right now.

Is it any wonder that we've got an almost immeasurable percentage of patients on home hemo? In fact, CMS doesn't have to wait for the implementation of an expanded bundle to get rid of that disincentive. That would cost $1,125,000 to pay just the actual costs for the training sessions for home hemo patients, according to the total number that were trained last year. That's 1/100th of a percent of the total ESRD budget. But I'm here to tell you that's a major reason why a lot of clinics don't do any home training, because when they eat that money up front, they know that they can make it back, but only if the patient lasts on that modality for about 18 to 24 months.

Well, with transplantation at 25 percent, mortality rate, and other reasons for transferring back to in-center hemo, there's a real risk that that patient won't turn profitable until they have to come off of that home modality, so why would people do that? They won't. If you simply covered those upfront costs, they'd be a lot more inclined to take that risk.

In terms of quality measures for our P4P, our original promise to Congress in getting the '73 reimbursement law was rehabilitation. My perspective is, whatever you're doing to that patient, if they are more likely to be rehabilitated or have a higher level of functioning, both of which are easily measurable, everything else you're doing is probably good. So to me, that and mortality, to support Dr. Owen's comment, are the two ultimate quality measures that should make the final cut. Hospitalization should as well. What should not make the final cut is paying people to reach a KTOV review that's determined for three-day-a-week dialysis. That's prehistoric based on what we know now. If you're going to use any quality measure for dose, it should at very minimum be weekly standard KTOV. Thank you.

CO-CHAIRMAN AUGUSTINE: Thank you very much. Leanne Zumwalt, you're up next from DaVita.

MS. ZUMWALT: I have some data that I'm going to leave with you, but I wanted to make a few comments regarding the challenges of implementing a bundle. First of all, this ESRD population is quite different than a typical Medicare population. You look at them

individually, they have changes in their cost structure over time, they have different issues as they progress through ESRD, and they are chronically ill.

In addition, the data presented today shows you that each patient is very different and their utilization of resources is very different. If you look at a historical bundle, they have looked for commonalities of care and cost. We see in this population that there's quite a bit of difference between care and cost needed, yet we're proposing only one single payment rate. I think the committee should take a look at the fact that in other payment systems, when there's a large distribution in care and cost items, the bundle has been broken down into separate payments, not one standard payment for a large group.

Some other things that need to be considered. This population is highly dual eligible in the Medicare field. About 15 percent of patients are Medicare/Medicaid. There's about 40 percent in this population, which means it comes with that kind of unique home and social characteristics. But in addition, will states pay the 20 percent co-insurance on a bundle? Currently today, many

states don't pay co-insurance on pharmaceuticals. We're not sure that they're going to pay the full new composite rate difference. What implications are there on this 20 percent? Theoretically you'll assume it's going to be funded. Will it in fact be funded? That research needs to be done.

Number of prescriptions, for example, in this population is about 6 to 8 oral meds. In the normal population it's probably plus or minus 2. Again, that's an indication that these patients are much more chronically ill and their needs are quite different than a Medicare population.

I found the discussion regarding the quality and the lack of relationship to payment just extremely disturbing. We know the one thing that's highly variable in the population from the data is EPO utilization, and we saw that there was a significant correlation to anemia outcome based on utilization. Yet again, this bundle isn't taking that into consideration. I think if you think about quality these types of items have to be considered.

The discussion around alignment of incentives with physicians is I think totally appropriate. They drive

a lot of the choice between a home modality and an in-center modality. They are the prescriber, as Chris pointed out, of the medications. They are not currently aligned necessarily with a bundle. If that compresses reimbursement to a facility, that will not drive, and shouldn't probably drive, a change in their prescription patterns, but yet will put the population at risk.

Another element that wasn't addressed today is that a very significant cost of our treatment, being EPO, is from a single-source manufacturer. They will by definition change their pricing. How does the bundle address that? How will the bundle stay in touch with what it cost a provider to provide that item? You cannot ignore that. We're the middle man. The doctor's ordering, the manufacturer's making decisions. We by definition have to hit a quality outcome if you choose to put it in there. If you don't, I think as Mike said, we're kind of at a point where most of our patients are hitting the target. We're in a box. If that continues to be a target, you need to address that point.

I think in terms of the data analyses here presented, still I have a little bit of concern around the

lab data. It wasn't clear to me that that was analyzed well and not sure where that's coming from, and who's ordering it, and how we ultimately drive the right behavior. I'm not against it being in the bundle, but I think more work needs to be done considering how we would actually change the behavior surrounding that. I think that's additionally true about the other items in 1D because they're ordered in a host of settings and how we might get our hands around that to rein that in I think is very challenging as an outpatient provider.

Probably the last point I'll talk about is pay-for-performance. I think they are important elements. They should drive proper clinical behavior. But if you're going to have those things in the bundle payment system, you must first decide that the unit of payment is correct. We believe that the current payment is clearly underfunded. That is presented in the MEDPAC work. We don't believe, as Mike pointed out, that there's room to decrease dose in anemia without changing outcome, so those things are very, very important as you move forward. Thank you.

CO-CHAIRMAN AUGUSTINE: Thank you, Ann.

SPEAKER: We have materials that I'll leave here

or you can pass it around, that summarize Leanne's points.

CO-CHAIRMAN AUGUSTINE: Thank you.

Dolph Chianchiano from the National Kidney Foundation.

MR. CHIANCHIANO: Thank you for the opportunity to address the board. In response to this morning's discussion, if all patients in a unit are not required to participate in the bundling demonstration, it is absolutely essential that every patient in a unit be entitled to elect to participate in the demonstration.

In regard to this afternoon's discussion and the agenda for the next meeting, I would like to draw your attention to some issues raised in the department's report to Congress, entitled, "Toward a Bundling Outpatient Medicare ESRD Prospective Payment System," as well as features of the RFA for the ESRD Disease Management Demonstration Project.

The report to Congress includes this warning: "Efforts to collect and evaluate quality measures will be essential to ensure that clinical outcomes do not decline as facilities respond to the new financial incentives created by a bundled prospective payment system." As Brady

mentioned this afternoon, we can't rely on the conditions of coverage to ensure quality assurance. If for no other reason -- it's very unlikely that the final rule will be published before the bundling demonstration begins.

As was noted, the bundling demonstration is not a disease management demonstration, however there are parallel considerations in the design of any demonstration project. The RFA for the ESRD disease management demo states that "CMS will monitor patient care to ensure that patients receive at least the same level of medically necessary services and medications, as determined by the patient's physician, as they received prior to enrollment." I think maybe the Advisory Board should consider such a proviso in the bundling demonstration.

The bundling demonstration should also be designed to monitor access to modalities, referrals for transplantation, patient satisfaction, and patient quality of life, as is in the case with the ESRD Disease Management Demo Project. Thank you.

CO-CHAIRMAN AUGUSTINE: Thank you very much, Dolph.

Finally, Jim Lordeman. He's a consultant to RCG.

MR. LORDEMAN: My name is Jim Lordeman. I'm an independent consultant, but I used to be employed by the Renal Care Group and now I'm an independent consultant that is representing the Renal Care Group. I wanted to be absolutely certain to have it made a part of the record, given the transaction that was announced a couple of weeks ago. I hope my consulting agreement will be continued. And in fact, every comment made by Dr. Lazarus has been brilliant, absolutely just sheer brilliant.

I think first an observation that probably nobody can do anything about, but I thought it might trigger some thoughts. If you look at MMA, Section 623e and f, the language used in those two sections are really strikingly different. 623e, which of course is the auspices of this group, is extremely specific. It says you will do this, there will be a demonstration, it will start on this date, it will include these things. 623f, asks for the report by October 1, it seems to suggest -- describe the feasibility, describe the mechanisms. And, oh, by the way, throw in some other things that the secretary may deem appropriate as he feels fit.

That's striking to me because it would be

interesting that in coming up with a report that has a little bit more room for creativity, if somehow in the demonstration project we didn't capture the opportunities to embody in the demonstration project some of that creative thinking, that might be able to be built into the report. Again, there's not a lot to do. That probably can be done by this committee. The language is pretty clear as to what this committee has to focus on, and I guess we're pretty much left with that.

I have another comment or question to ask the committee to try to think about. I'll phrase it this way just to maybe stimulate the thoughts. It's probably a wacky way of stating it. If somehow the KECC people could build this brilliant model that could calculate the remainder of lifetime costs for a patient as soon as they hit creatinine clearance of, let's say, maybe 30 or 60, some number of serious degradation of kidney function -- if we then knew this patient is going to cost $417,000 for the rest of their lives -- if we then knew that amount and prepaid that to some team of providers undoubtedly led by a nephrologist, what behaviors do we think we would then see, given that kind of an incentive?

Obviously that is totally non-practical. But as you think about what behaviors that might incentivize, I think it would be very clear that a lot of behavior changes would occur in the CKD arena, and I would I guess urge this committee -- again, we're kind of stuck with a bundle project, and it's got to have this and it's got to start here. But at least to the extent that pay-for-performance initiatives can be layered on top of a new bundled mechanism, I think, in terms of where the big impacts can be --

I read the transcript of the first meeting. I'm sorry that I missed it, but everyone spoke about kind of broader themes and issues in improving what we do for these patients. I think the big opportunity is likely to result from things other than is it 1A, or 1C or 1D. I think this is a little bit tinkering around the edges when there's bigger issues that can have a bigger impact. But nonetheless, I recognize how difficult this is and the directive that's been given, and appreciate all the work of the committee. Thanks.

CO-CHAIRMAN AUGUSTINE: Thank you, Jim. In fact, as you pointed out happily, this group has not been

chopped, and there's a lot of serious, thoughtful deliberation here, and it doesn't just pertain to the very concrete bundle recommended in E, but a different prescription is given in F, and then there's a cross-reference as well. So there's a lot of ambiguity which allows a little more latitude to this group to provide a recommendation that we think is in the best interest of the program, the providers and the patients, and meets the IOM's aims on the back wall. So thank you very much for your comments, everyone.

Bob, closing remarks you'd like to make or wrap up?

CO-CHAIRMAN RUBIN: Although it sometimes didn't feel like it, I think we got a lot accomplished today. It's a lot of data to digest, and I think a good to-do list for the staff in preparation for the upcoming meeting. Clearly the committee members actually read this two inches or so of material that was dispatched to us, and it was not easy reading. So thank you.

MS. MAGNO: I have just a closing comment. The next meeting is scheduled for July 14th and 15th. We expect it to be at the BWI Marriott Hotel, which all of you would

have passed on your way here today. The details with respect to meeting times will be published in the *Federal Register* the end of June. The fourth Friday in June is when we expect to publish the notice in the Federal Register, and that will have the exact times that the meeting will start and end, both days. Thank you.

CO-CHAIRMAN AUGUSTINE: I don't have any profound words. I just want to thank everyone for letting us have a little bit of your time today. As always, anytime we get this community together it's an enlightening discussion. And I am more proud of the community that I am from. Thank you very much. We'll see you at the next meeting. We are adjourned.

(Whereupon, at 4:42 p.m., the meeting was adjourned.)

C E R T I F I C A T E

This is to certify that the foregoing proceedings of an advisory board meeting before co-chairmen Robert J. Rubin, M.D. and Brady Agustine, in the matter of Demonstration of a Bundled Case-Mix Adjusted Payment System for End Stage Renal Disease (ESRD) Services, held on Tuesday, May 24, 2005, were transcribed as herein appears, and that this is the original of transcript thereof.

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Lisa L. Dennis, CVR