

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

Holiday Inn BWI Airport
890 Elkridge Landing Road
Linthicum, Maryland 21090

Tuesday
May 24, 2005

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

P R E S E N T

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

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

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

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

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

5 DR. LAZARUS: So moved.

6 DR. WISH: Seconded.

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

9 (Chorus of ayes)

10 CO-CHAIRMAN RUBIN: Opposed? Okay.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 1B took a next category of sort of major drugs
6 that had been identified by the Officer of Inspector
7 General and in other studies that are significant sources
8 of costs, and that would include primarily Levocarnitine,
9 Alteplase, and Vancomycin. Then the lab tests related to
10 that, which we've classified generally as either lab tests
11 related to infection or lab tests related to carnitine.

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

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

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

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

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

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

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

5 Paul?

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

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

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

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

19 So that's essentially the notion here.

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

1 DR. LAZARUS: Probably, yes.

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

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

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

4 CO-CHAIRMAN AUGUSTINE: Henry?

5 MR. BACHOFER: Yes?

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

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

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

1 the services that are included within the bundle.

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

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

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

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

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

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

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

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

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

20 MR. BACHOFER: No, there is not.

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

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

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

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

6 MR. BACHOFER: Okay.

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

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

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

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

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

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

1 start with MCP and work our way up.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

16 Brady?

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

1 that would impact MCP.

2 SPEAKER: MCP was designed that way.

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

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

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

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

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

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

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

7 CO-CHAIRMAN RUBIN: Brady's number was 68 to
8 70 percent, is what the MCP represented.

9 SPEAKER: I think that's high.

10 SPEAKER: Seventy sounds high.

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

12 SPEAKER: It might be 60 percent of outpatients.

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

17 MR. BACHOFER: Okay.

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

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

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

2 CO-CHAIRMAN RUBIN: Absolutely.

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

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

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

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

16 MR. BACHOFER: Okay.

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

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

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

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

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

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

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

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

5 SPEAKER: The 20?

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

9 MR. TURENNE: It's very small.

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

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

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

11 The next question is how much variability is
12 there within these various categories. What this slide
13 shows is the various points along the distribution, if you
14 will, for composite rate payments, EPO payments, and MCP
15 payments. The green area reflects the interquartile range
16 or is spaced from the 25th to the 75th percentile. So half
17 of all patients fall within the green range. The bar that
18 divides the green range is essentially the median for each
19 of these. What you can see is that for the composite rate
20 you have a median value that's relatively small, about
21 5 percent variation on either side of the median value.
22 Beyond that, the patients who are between the 5th and the

1 25th, 75th and the 95th percentile add some variation to
2 that. But, again, it occupies a very small range.

3 For EPO, in contrast there's a very broad range
4 of variation across patients in the interquartile range
5 around the median value of about \$500 per month. Bouncing
6 down to the MCP payment again, it looks much more like the
7 composite rate. In fact, it shows a little bit smaller
8 amount of variation than the composite rate but not a great
9 deal. The reason for the differences is simply a scaling
10 effect, and if you show that as percentage terms, you
11 actually can see that. In both cases of composite rate and
12 MCP payments, 50 percent of all patients are varying by
13 less than 5 percent on either side. In contrast, if you're
14 looking at the EPO payments, half of patients fall between
15 \$240 and \$950, so over a much broader range.

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

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

1 basically labor, exception.

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

4 MR. BACHOFER: It's payments.

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

6 MR. BACHOFER: No, I believe we inflated for the
7 80 percent. I believe we added that back in. So it's the
8 total amount before cost sharing. It's what we call MAC,
9 maximum allowable --

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

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

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

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

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

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

1 not used.

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

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

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

1 claim.

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

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

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

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

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

18 MR. BACHOFER: Right.

19 CO-CHAIRMAN RUBIN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

21 MR. BACHOFER: Sure.

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

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

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

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

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

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

22 MR. BACHOFER: Right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 CO-CHAIRMAN RUBIN: Assuming we decide to include

1 vascular access at all.

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

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

1 Bob?

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

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

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

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

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

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

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

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

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

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

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

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

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

5 Does anyone have any general comments? Paul?

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

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

1 of resources, we have to implicitly assume that.

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

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

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

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

16 MR. BACHOFER: I apologize for that.

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

18 MR. BACHOFER: All right. This next section,
19 we'll sort of shift focus a little bit. Instead of looking
20 at those two broadly expanded bundles, we'll be looking at
21 the descriptive data for the more narrowly-defined bundles,
22 1A through 1D.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 MS. RAY: Yes.

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

20 MS. RAY: Yes.

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

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

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

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

15 MR. BACHOFER: Right.

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

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

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

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

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

9 CO-CHAIRMAN RUBIN: For sure.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3 Finally, what is the effect of bundling on the
4 50/50 rule? This was the point in which I saw a couple of
5 people's eyes light up. Generally, it would make the 50/50
6 rule moot. It would make it go away in effect because all
7 of the lab tests would be bundled into the payment, so
8 therefore there would be no need to evaluate individual lab
9 tests to determine whether or not they would be billable.

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

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

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

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

8 Brady has indicated in conversation that based on
9 past discussions of the 50/50 rule that probably the
10 majority of multichannel tests are disallowed under the
11 50/50 rule. But whether that means 70 percent, 80 percent
12 or 55 percent we're not really sure at this point in time,
13 but we're continuing to try to get a handle on that.

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

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

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

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

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

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

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

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

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

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

7 MR. CANTOR: Can I ask one question?

8 MR. BACHOFER: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

3 MR. BACHOFER: I think we have two different
4 perspectives here. One way of coming up with per-month
5 data would be to look at patients average use of services
6 over the course of an entire year, and basically divided by
7 12.

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

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

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

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

1 June.

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

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

12 DR. WOLFE: We did take the full year.

13 SPEAKER: We did take a full year.

14 DR. WOLFE: They did take the full year.

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

21 SPEAKER: That's correct.

22 MR. BACHOFER: Right.

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

8 (Whereupon, there was a brief recess.)

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

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

22 CO-CHAIRMAN RUBIN: The other thing that I wanted

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

9 Henry, can you continue?

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

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

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

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

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

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

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

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

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

14 The drug amount under Bundle 1A for those three
15 drugs is \$1,082 per month, labs add \$64, and that's just
16 the labs for anemia and Vitamin D. The total therefore
17 becomes \$2,828. Bundle 1C has a drug amount of \$1,100 that
18 includes the first three drugs. It only increases the
19 total amount for drugs by about \$18 per patient month, and
20 it adds only \$11 per patient month for the two categories
21 of the lab tests that were added into the bundle, namely
22 lab tests for infection and lab tests for carnitine.

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

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

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

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

1 MR. BACHOFER: 4 x 4 gauze pads.

2 SPEAKER: Syringe they use to inject EPO.

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

5 SPEAKER: Stuff.

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

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

1 everything in terms of that's being added in. The
2 incremental amounts being added on, from going from 1A to
3 1B, adds only \$29 per patient month. It adds only \$43 per
4 patient month to go from 1B to 1C. And it adds obviously
5 only the 16, and only a part of that actually would be
6 things like non-radiology purposes. So it's actually a
7 relatively small dollar amount. Again, I recognize that as
8 you multiply this by millions of patients, 2.9 million a
9 month, these things have a way of adding up. Again, these
10 are still for HD patients for four months only and not
11 months that include any kind of events.

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

19 This is perhaps not the most eloquent way of
20 presenting this kind of data, but these are essentially
21 percentile points for the 25th, 50th, 75th and
22 95th percentiles. As you can see in the figure, the

1 composite rate shows relatively little variation; we
2 already saw that in an earlier slide. The 25th percentile
3 is \$1,578. The 75th percentile is \$1,764, so that the
4 total spread there for 50 percent of the patients is only
5 \$186 per patient month. Again, it's about 6 percent, or
6 thereabouts, of the median.

7 DR. EGGERS: EPO.

8 MR. BACHOFER: EPO is in Bundle 1A.

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

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

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

13 MR. BACHOFER: Correct, and it is equal.

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

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

18 But if you look at 1A, the 25th percentile is
19 \$2,229 versus the 75th at \$3,163, so that you have an
20 overall spread of \$934, roughly twice what the median value
21 is. So half of the patients fall within a range of about
22 \$1,000 on either side of the median and half of all the

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

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

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

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

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

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

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

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

9 DR. OWEN: I'll be a provocateur.

10 MR. BACHOFER: That's fine.

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

14 MR. BACHOFER: Okay.

15 DR. WISH: CPM has that data.

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

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

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

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

22 The next three categories of drugs, which are

1 included in Bundle 1B, Levocarnitine, Alteplase, and
2 Vancomycin, show a very different pattern. A minority of
3 patients over the course of a year receive those drugs,
4 although Vancomycin is used by about 28 or so percent of
5 all patients. But Levocarnitine Alteplase are used by much
6 smaller percentages. And strikingly, less than
7 5 percent -- for the most part, although Vancomycin shows a
8 little bit higher -- of patient months involve those drugs.
9 So again, although those drugs account for a relatively
10 small amount of average added costs, when they occur they
11 can add quite a bit to the cost for any given moment, which
12 is the consideration I may want to come back to.

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

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

20 DR. LAZARUS: And reflect episodic
21 administration?

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

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

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

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

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

1 DR. EGGERS: Page 3?

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

3 If we look at the percentile breakdown of these
4 various categories, consistent with what we saw previously
5 and as Paul Eggers pointed out, if you look at EPO, the
6 25th percentile is 240, the 75th percentile is 953. Again,
7 you have them across a very broad range; you've got a
8 significant amount of variation. If you look at Vitamin D,
9 the 25th percentile is actually zero, so fewer than
10 25 percent of the patients are using it. The 50th
11 percentile is 125 versus 301 at the 75th. So 25 percent of
12 patients are using more than \$301 of Vitamin D per month.
13 For iron you have a similar pattern in that it's used by 25
14 percent of patients. More than 25 percent receive none in
15 patient months, the median value is 66 and 75 percent of
16 patients have usage at \$204 or more.

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

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

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

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

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

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

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

14 But we're looking, again, at more than 75 or
15 70 percent or so of patients who are actually receiving
16 tests in that category. However, again, consistent with
17 this sort of distinction between the first Bundle 1A being
18 more chronic in their character and being used month after
19 month and Bundle 1B, the percentage of patient months that
20 involve claims for these lab tests in Bundle 1B is only
21 about 20 percent or one out of every five months.

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

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

9 If you look at the percentile points on variation
10 for these lab tests, you again see a somewhat different
11 pattern in some way. Claims for anemia tests are being
12 submitted in more than three-quarters of patient months as
13 was seen previously. On average you're seeing \$28 and \$35
14 respectively. But in 25 percent for months, claims for
15 anemia tests exceed \$40, and then 5 percent they exceed
16 \$58. And in Vitamin D tests, a sort of similar pattern,
17 5 percent a month they exceed \$79 per month.

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

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

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

7 MR. BACHOFER: These are separately billable
8 labs.

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

12 MR. BACHOFER: Those are not shown here.

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

15 MR. BACHOFER: Exactly.

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

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

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

7 DR. WISH: That is surprising.

8 CO-CHAIRMAN RUBIN: I would agree with that.

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

12 MS. CUELLAR: We are.

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

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

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

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

1 in the composite rate is?

2 SPEAKER: Once a week.

3 CO-CHAIRMAN AUGUSTINE: It's weekly?

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

6 MR. BACHOFER: Yes.

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

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

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

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

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

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

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

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

5 SPEAKER: Those are iron, not --

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

10 MR. BACHOFER: Right.

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

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

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

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

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

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

22 DR. LAZARUS: Take the simplest, 1A.

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

3 MR. BACHOFER: Right, subject to revision.

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

6 MR. BACHOFER: Right.

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

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

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

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

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

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

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

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

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

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

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

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

7 DR. EGGERS: You dropped what?

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

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

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

1 way to do business.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 high using EPO units?

2 MR. BACHOFER: No.

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

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

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

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

12 DR. OWEN: All right, excellent.

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

15 (Laughter)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 outliers.

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

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

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

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

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

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

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

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

1 including in the bundle?

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

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

7 MS. GREENSPAN: Okay.

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

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

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

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

11 DR. WHEELER: Yes, that's right.

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

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

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

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

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

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

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

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

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

1 give me more specificity as to what was done there?

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

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

1 over-identification otherwise.

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

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

6 DR. HIRTH: Thank you.

7 CO-CHAIRMAN RUBIN: Okay, Jack.

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

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

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

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

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

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

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

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

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

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

3 Let me turn it over to Richard.

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

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

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

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

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

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

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

13 Here's a little bit more descriptive data before
14 we get into the models. This block just indicates at what
15 level does the variability in the raw data occur. If we
16 look at the box and whiskers on the left that's labeled
17 "patient month," that essentially says that if we look at
18 kind of the broad range there, the 5th percentile to the
19 95th percentile, you've got a range of about \$25 to \$250
20 per session. That's the variability between the patient
21 month at the 5th percentile and the patient month at the
22 95th percentile.

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

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

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

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

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

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

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

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

3 The characteristics such as the early months of
4 renal replacement therapy, which are clearly the first six
5 months, indicate spending at greater than 10 percent above
6 the baseline level. Women have higher spending. We
7 actually put in an interaction term of females 18 to 44
8 have particularly higher spending on anemia therapy.
9 Larger patients had higher spending. Those with lower
10 baseline hematocrit had higher spending. The comorbidities
11 that had the biggest effects are infections, several
12 bleeding conditions, anemias and hematologic cancers, and
13 then months following hospitalization. If you were
14 hospitalized the month before, you tended to have more than
15 10 percent elevation in your EPO spending per session in
16 the subsequent month.

17 I'm going to highlight a few of the things that
18 had relatively smaller effects that didn't make our
19 10 percent cut. Age didn't make the 10 percent cut. Race
20 ethnicity. With the exception of a very small group of
21 Pacific Islanders, all the race ethnicity effects were less
22 than 10 percent in magnitude; most of the measures of

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

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

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

18 This is essentially what I call the null model.
19 This is just the raw, unadjusted data, so there's no
20 case-mix adjustment here at all. We've got nearly
21 2 million patient months that focuses on Bundle 1C and uses
22 payment per session as the dependent variable for HD

1 patients.

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

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

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

1 level, for patient to patient, it's about \$48. If we look
2 within patients, the month-to-month variability is about
3 \$40 per session.

4 DR. LAZARUS: This includes 13 treatments?

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

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

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

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

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

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

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

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

7 One thing that I want to draw your attention to
8 is the correlation of prediction errors. What I mean by
9 the correlation of prediction errors is we take a model,
10 and let's say the model predicts that you're going to cost
11 \$150 a session. So it predicts you're going to be about
12 \$50 more expensive than the average patient. Suppose,
13 though, this month you actually cost \$200? Essentially the
14 model under-predicted your real cost by 50 bucks. It said
15 you'd be about \$50 more expensive than average, but in
16 reality you are about \$100 more expensive.

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

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

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

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

19 DR. HIRTH: 0 to 1 would be from 0 percent to
20 100 percent. It's just reporting it in percentages. You
21 could think of 1 as being 100 percent.

22 MR. CANTOR: So this is really 7 percent.

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

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

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

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

20 SPEAKER: In '96.

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

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

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

5 CO-CHAIRMAN RUBIN: Dr. Owen?

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

9 CO-CHAIRMAN RUBIN: Okay. Dr. Wolfe?

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

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

15 CO-CHAIRMAN AUGUSTINE: I just want to say 10,
16 15, 25 percent is ideal. I mean, it's all relative. If
17 we're in an experimental setting, then of course we're
18 shooting for 80, 85, 90 percent. But this is observational
19 data with a myriad of factors that we absolutely have no
20 idea about. I think we're not doing too bad.

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

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

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

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

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

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

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

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

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

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

13 DR. WOLFE: Perhaps, but let me repeat it. It's
14 101 on average, but the model says it's 101 plus 22 for
15 some patients and minus 22 for some patients. That's what
16 we can predict based upon the characteristics. In
17 addition, the actual payments unfortunately weren't exactly
18 whatever we predicted. They varied above and below that by
19 about plus or minus \$40 from patient to patient,
20 unexplained. So the bottom part is unexplained variation,
21 some of which is due to facility practice possibly and some
22 of which is due to patient characteristics.

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

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

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

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

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

18 What we did is just randomly decided to trim out
19 the top 1 percent of spending per month. So we took the
20 1 percent of months that were the most expensive in dollars
21 per session, kind of just arbitrarily defined that as sort
22 of an outlier payment level and said how well does a

1 case-mix model do at explaining the other 99 percent that
2 we didn't trim out as compared to when you use the
3 100 percent of the data and what happens to the
4 variability.

5 Essentially, the trim level is at about \$320 per
6 session of spending, so it's a pretty high spending. So if
7 three-quarters of it is EPO, that would be about 24,000
8 units a session, so it's about five times the median level.
9 It brings the average payment down by nearly \$4, from about
10 \$73 down to \$69. The R^2 tells us when we use all the data,
11 we're not quite as good at explaining EPO and iron spending
12 as we do when we trim out a high 1 percent, and high
13 1 percent is a little bit harder to explain than the
14 average patient month.

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

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

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

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

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

1 to unit of payment.

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

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

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

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

1 session model, but it still falls short. It's about 5.5 or
2 6 percent when you add the type of month.

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

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

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

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

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

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

10 DR. EGGERS: So Medicare is paying only
11 40 percent for PD what it pays for --

12 DR. HIRTH: Separately billable.

13 DR. EGGERS: Sorry.

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

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

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

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

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

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

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

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

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

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

1 trying to predict costs.

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

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

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

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

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

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

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

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

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

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

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

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

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

1 there or not? Should other measures be there?

2 There were some of the issues that Jack raised at
3 the beginning. Should average payment be based on current
4 practice? All of our data is based on current practice;
5 2003 practice -- I shouldn't even say current
6 practice -- or some indication of what a clinically
7 appropriate practice might be.

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

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

20 DR. HIRTH: Sure.

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

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

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

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

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

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

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

1 three tries to come up with a good measure?

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

3 CO-CHAIRMAN RUBIN: Okay.

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

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

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

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

19 DR. HIRTH: That was not looked for.

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

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

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

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

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

17 DR. HIRTH: I was talking about hospitalization.

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

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

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

4 DR. HIRTH: Yes.

5 DR. OWEN: So you had BMI?

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

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

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

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

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

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

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

8 (Whereupon, there was a brief lunch recess.)

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

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

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

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

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

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

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

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

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

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

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

11 DR. OWEN: I think they should be separated.

12 CO-CHAIRMAN RUBIN: Yeah, I agree.

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

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

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

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

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

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

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

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

22 CO-CHAIRMAN AUGUSTINE: And that is something

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

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

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

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

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

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

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

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

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

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

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

21 CO-CHAIRMAN AUGUSTINE: Other comments?

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

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

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

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

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

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

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

1 way to the system.

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

10 Now is that a correct statement, Dr. Wolfe?

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

17 DR. LAZARUS: But it should be.

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

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

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

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

12 DR. LAZARUS: What services are those?

13 DR. WOLFE: EPO, Vitamin B.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 CO-CHAIRMAN AUGUSTINE: One of the issues we're
12 going to have is how we're going to administer the initial
13 method. That's the only regulation that we have that we
14 could do this. An initial method, for those of you who may
15 not know, is basically an artifact that's been around since
16 1983, where if every single one of facility physicians
17 choose to build an initial method, they can build through
18 the facility's composite rate. I don't know if it's add
19 on. I guess it's an add on. It's never been administered.
20 They would get paid an equivalent of about 130 bucks a
21 month. That would give us some flexibility and we could
22 change the numbers in there. But basically they agree to

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

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

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

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

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

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

13 CO-CHAIRMAN RUBIN: I don't think so. I don't
14 want to put words in his mouth. What Mike is saying is the
15 degree to which physicians participate will clearly affect
16 the willingness of any individual provider's facility to
17 participate in the demonstration. In essence, the ideal de
18 facto position would be the initial method, i.e.,
19 100 percent participation.

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

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

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

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

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

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

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

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

1 that CMS will offer us?

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

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

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

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

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

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

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

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

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

22 MS. CUELLAR: If the physicians are compelled to

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

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

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

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

20 DR. WISH: Seconded.

21 CO-CHAIRMAN AUGUSTINE: Any discussion? Any
22 opposed?

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

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

8 CO-CHAIRMAN RUBIN: I guess my amplification of
9 that would be that we ask the staff to come up with a
10 proposal for the July meeting that would meet the goals
11 that we've just articulated, and then at that point you can
12 do whatever you feel like you need to do. DR.

13 EGGERS: Groups typically give a group recommendation?

14 SPEAKER: Yes.

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

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

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

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

1 we did, it would be a split vote.

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

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

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

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

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

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

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

8 SPEAKER: Are we voting or punting?

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

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

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

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

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

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

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

1 would interest providers.

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

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

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

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

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

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

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

9 DR. EGGERS: Including pay for all the
10 hospitalizations.

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

17 DR. EGGERS: -- supposed to do that?

18 CO-CHAIRMAN RUBIN: Nobody came to the party.

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

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

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

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

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

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

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

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

12 CO-CHAIRMAN RUBIN: Right.

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

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

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

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

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

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

17 SPEAKER: Other comments on vascular access?

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

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

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

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

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

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

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

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

22 In effect, we would be have to have the ability

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

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

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

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

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

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

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

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

20 DR. OWEN: Yes.

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

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

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

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

11 CO-CHAIRMAN AUGUSTINE: Thank you.

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

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

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

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

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

16 DR. LAZARUS: Who's getting incentivized when?

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

1 vascular access.

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

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

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

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

1 coordinating the care of that beneficiary.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 MR. BACHOFER: I was actually just touching on

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

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

1 order to process according to that definition.

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

10 Is there a second?

11 DR WISH: Seconded.

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

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

1 to be a challenge, never mind getting better.

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

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

21 Other comments?

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

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

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

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

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

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

16 Any further comments?

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

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

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

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

11 CO-CHAIRMAN AUGUSTINE: There are times I refer
12 to it as home and people get confused, and times I refer to
13 it as PD. I think it's either in-center or not in-center;
14 I mean home. When we're talking about home the profiles
15 are vastly different, from all of the different home
16 modalities, as opposed to in-center.

17 DR. LAZARUS: So you're suggesting that a
18 dialysis unit would enter this demonstration only for the
19 in-center hemo patients, and if they have a large PD
20 program, they would have a separate demonstration; they
21 could opt for either one, and you would not put that as one
22 entire program?

1 CO-CHAIRMAN AUGUSTINE: This isn't a
2 recommendation. Actually, I would like to hear this out
3 more. But the payment would be different for PD patients
4 than it would be for hemodialysis, and it would reflect the
5 average level of PD patients per month or per session
6 across the country with certain case-mix factors that will
7 differ from PD to hemodialysis.

8 DR. LAZARUS: Then your suggestion is it's going
9 to be lower or higher?

10 CO-CHAIRMAN AUGUSTINE: It would be reflective of
11 what an efficient provider would provide for PD.

12 SPEAKER: You're talking about the composite
13 rate; it would be 40 percent as much.

14 DR. BURKART: But is that difference truly
15 related to need or availability? What drives that
16 difference? I think if we're going to pay differently we
17 have to know what drives those differences. Is it that the
18 PD patients need less or they're not given the same amount
19 because of access to care?

20 CO-CHAIRMAN AUGUSTINE: Or all the above.

21 DR. BURKART: Or all of the above. If there are
22 differences that don't have to do with patient care, we may

1 be subliminally preventing access to care. If we change
2 the payment for reasons that have nothing to do with
3 medical outcome or medical need, we may affect who does the
4 different therapies.

5 CO-CHAIRMAN AUGUSTINE: I agree with you
6 completely. That's why I'm saying that we need to be much
7 more thoughtful on this issue. I think all of us agree
8 that home therapies are not used near as much as they
9 should, and there's a huge amount of opportunity there.
10 That may be something that could be looked at in P4P as
11 well, not that P4P is a panacea. But paying the same for
12 hemo and PD, considering the fact that they're very
13 different populations, is something that's kind of hard to
14 justify.

15 MS. ROBINSON: I would just be really concerned
16 about anything that we do that would not allow patients to
17 know about home therapies. I mean, it's bad enough right
18 now for patients to learn in certain facilities. If we're
19 not going to help to get the home therapies out there,
20 that's detrimental to patients.

21 CO-CHAIRMAN AUGUSTINE: I agree completely. CMS,
22 Congress, and everyone has basically weighed in on this

1 issue of MEDPAC. We've all said that we would like to
2 create an environment where PD can grow. Ironically, the
3 payment system, which CMS administers, has not done that
4 over the past years. Part of that is congressional,
5 statutory, part of that is CMS.

6 We'd like to have an environment where we can
7 have an environment that fosters home therapies. We've got
8 a lot of opportunity for improvement, and we need to think
9 about how we can do that in this demonstration and
10 recognize the uniqueness of the home program, but also
11 provide an environment where they can be incentivized as
12 well without tying them to hemodialysis. They're very
13 different populations.

14 DR. BURKART: For instance we have a composite
15 rate for the treatment and then we have rates that you pay
16 for the use of drugs and layouts. A lot of what happens in
17 hemodialysis is related to these add-ons, what we would
18 propose to be in Bundle 1A, 1B and 1C.

19 In PD or home therapies we haven't had so many of
20 those opportunities, but there have been innovations in
21 home therapy; daily dialysis, new dialysis solutions for
22 PDs. And yet those things are in the composite rate.

1 I think if we're going to say that we need to do
2 something different for home therapies, then we have to
3 start at square one I think and look at the therapies and
4 what the therapies actually are. We're willing to come up
5 with Bundle 1A or 1B based on what we were reimbursed in
6 2003. We're just picking 2003; we're not picking 1995;
7 whereas what we can do in our home therapies is based on
8 the composite rate, which there's been no really resetting.

9 If we're not able to use the separately billables
10 and we want to treat them different, I think we have to be
11 prepared to start from square one and see what does it
12 cost, what are the costs, and look at it completely
13 differently because we've not been able to have any effect
14 in what we do that comes under the composite rate in the
15 home therapies.

16 CO-CHAIRMAN AUGUSTINE: Actually, you raise a
17 very good point. In part, one of the reason why we're
18 interested in expanded bundle is that our payment policy
19 actually has an impact on practice patterns. For example,
20 there's not a lot of flexibility. There are a lot of
21 providers out there that would like for a certain subset of
22 their patients to do more frequent dialysis, other types of

1 modalities which are not really amenable to our current
2 payment system. That's one reason why the expanded bundle
3 provides a little bit of flexibility, like a monthly
4 payment or a weekly payment, whereas you can choose which
5 frequency and duration you would like that's in the best
6 interest of the patient. So that is something we need to
7 consider.

8 Now, how we do that is something I don't have the
9 answer to. KECC, if you have kind of looked at home
10 therapies, PD. What have you learned above and beyond
11 potentially what you raised today on the few slides that we
12 saw?

13 DR. WOLFE: We have not looked at home therapies
14 other than PD really in any detail. The bills come in, to
15 a large extent, through supplies rather than through the
16 dialysis center. It's more episodic as those supplies come
17 in. It's not as evenly shown and it's harder to know if
18 we've got everything. I'll say we're less confident about
19 our ability to know the right level of payments that are
20 being made for those patients.

21 DR. EGGERS: The vast majority of the tables that
22 we saw today -- I think it was parallel bars and \$103 or

1 whatever it was -- did that include Type 1 PD patients?

2 DR. WOLFE: No.

3 DR. EGGERS: So that was all hemodialysis. Well,
4 in-center hemodialysis.

5 CO-CHAIRMAN AUGUSTINE: One of the issues we have
6 general -- I don't know if it's OIG or GAO. They found
7 that Method 2, even though it had good intention, did not
8 achieve its intended purpose, which was it would lower cost
9 sharing for our beneficiaries, and it did not achieve that.
10 In the aggregate, actually patients paid more under
11 Method 2 than they did under Method 1.

12 There have been some changes in the program of
13 late as far as instead of there being a package of services
14 in Method 2, actually having people bill them separately
15 and have helped out there. From an administrative,
16 oversight perspective, Method 2 is very difficult because
17 you've got another set of contractors to deal with. You've
18 got FI, carriers, and now the DMRCs. Doing policy changes
19 with another set of contractors is difficult, number one.
20 And number two, from a quality perspective it makes it even
21 more difficult as well because there's kind of a break up
22 of who actually is in charge of the patient and who's held

1 accountable. So Method 2 is something that I would
2 recommend that we not use for this demonstration.

3 CO-CHAIRMAN RUBIN: I have a few questions that
4 I'd like to pose to the people at that table over there
5 just to expose my ignorance here.

6 If we were to ask you for the July meeting to
7 prepare data that would reach to the cost of peritoneal
8 dialysis and/or home hemodialysis, could you do it with any
9 degree of confidence?

10 SPEAKER: You said cost. Do you mean cost?

11 CO-CHAIRMAN RUBIN: I meant Medicare allowable
12 cost, or payment, yes. Actually, not actual payment; it's
13 what would be allowable.

14 MR. BACHOFER: I think the short answer to the
15 question is that there are some things that could be done
16 fairly readily and there are some data that are already
17 included in the notebook that you have. This actually is
18 comparing HD to PD. The numbers across the bottom, all odd
19 numbers are drug amounts -- I'm sorry for the lack of
20 formatting -- and all even numbers are lab test amounts.
21 Those are the three major bundles. So 1 and 2 are bundled
22 1A. Numbers 3 and 4 are bundled 1B, and numbers 5 and 6

1 are bundled 1C.

2 Just very quickly and very graphically, what this
3 is suggesting is that there is an enormous difference in
4 the per month use of EPO, iron and Vitamin D, which is
5 really the first set of bars there, PD versus HD, the blue
6 bars being PD and the reddish bars being PD. If you go
7 across the rest of them, particularly in lab tests, there's
8 very little difference in the average cost per month, or
9 average payment amounts, or max per month if you will,
10 between the two categories. It's very largely driven by
11 the first category of drugs.

12 The question that that leaves me with as I look
13 at that is, is this because PD patients are being under-
14 treated for anemia and the other things that they receive
15 these for? Is it because they have lesser need? Is it
16 because that need is being more efficiently met? We can't,
17 I don't believe, answer any of those questions out of the
18 data that we have in terms of the raw claims data.

19 CO-CHAIRMAN RUBIN: You can't? You don't have
20 hemoglobin and hematocrit data for PD patients?

21 MR. BACHOFER: We could try to construct some
22 measures like that.

1 CO-CHAIRMAN RUBIN: Wait, wait, wait. I'm sure
2 you do have that.

3 DR. WOLFE: We do have that, yes. We could try
4 to put something together.

5 CO-CHAIRMAN RUBIN: So can you take Database A
6 and Database B and switch them together to answer the kind
7 of questions you're asking?

8 DR. WOLFE: I heard several different issues
9 being asked here. We can address whether hematocrits are
10 being achieved, and the short answer is, yes, they are
11 being achieved.

12 CO-CHAIRMAN RUBIN: Right.

13 DR. WOLFE: I think what Henry was referring to
14 is we aren't sure that we're capturing all of the drugs
15 there because we're only getting the IV drugs for the PD
16 patients. I've understood that some of these drugs are not
17 giving IV to PD patients but are taken orally.

18 CO-CHAIRMAN RUBIN: That's correct.

19 DR. WOLFE: So there's a substitution going on
20 here and we don't capture those other drugs, which is I
21 think what Henry was getting at.

22 CO-CHAIRMAN RUBIN: I understand that. But we

1 could have enough elements so that if we chose to have a PD
2 bundle, we would know what we had in a base and what we
3 might choose to put in. If we decide that one of the
4 things we want to do is incent people to use more PD, we
5 could align that dollar amount in a way that we think could
6 achieve it.

7 In other words, what I'm saying is that right
8 now, today, we don't seem to have actionable data. At
9 least I certainly don't feel we have actionable data. What
10 I'd like to see in July is the development of some
11 actionable data so that we can think about how we want to
12 deal with this whole issue since my understanding is that
13 there's a movement afoot to try to get more people to go
14 home, or at least start at home, whether it's PD, or home
15 hemo, or whatever. But right now I don't see how we could
16 do it.

17 DR. EGGERS: I make certain assumptions here.
18 One is that OMB isn't going to allow CMS to do anything
19 that isn't payment neutral on the whole thing. But if you
20 were to mush them together in the analysis that you have
21 right now, and you include all home patients -- home
22 patients is 7 percent of patients. So you have a weighted

1 average really of those two bars there. Give 7 percent of
2 your weight to the blue bar and 93 percent of your weight
3 to the magenta bar there, and your bundle payment 1D,
4 whatever it is, is going to shrink a little bit, and you
5 could apply that to all patients. And then the facility
6 gets a little bit less, but has all patients treated the
7 same. That's what's going to happen when they crunch the
8 numbers, as opposed to embedding in the payment system that
9 difference there, assuming that it's correct. And I'm
10 hearing now a great deal of enthusiasm for that.

11 DR. OWEN: I think we're probably comparing
12 fruits, but are we comparing apples and oranges? First of
13 all, isn't the EPO administered subcutaneously, and we're
14 comparing an IV versus a subcutaneous route of
15 administration? Secondly, I may be in error on this, but I
16 don't think the percentage of patients achieving benchmark
17 hemoglobins is the same, so are you going to forecast that
18 out? I'm just saying, I don't think you can use this data
19 to try to rate set for one unless you change the rules for
20 the rate setting of the other.

21 MS. CUELLAR: And the same for the iron studies
22 on those patients, and the calcium phosphorus, and the

1 PTHs, and all of those issues. Those patients are taking
2 oral medications or not taking them at all, more likely,
3 more than likely not getting the drug at all.

4 DR. EGGERS: What's your solution in terms of
5 incorporated PD patients? Pay more for them?

6 DR. OWEN: I don't know, Paul, because I don't
7 know if it's linear. We talked about dose response scores
8 here. I don't know if it's linear or not. I guess what
9 I'm saying is to use historic data to try to rate set when
10 my benchmarks aren't being met scares me.

11 CO-CHAIRMAN AUGUSTINE: Especially when the Part
12 D benefit is going to be coming on line at the beginning of
13 next year as well, which will include coverage for those
14 oral drugs.

15 DR. EGGERS: But we don't know that EPO isn't
16 used 30 percent higher than it should be, right? So why
17 are we embedding that into the new system? Why don't we
18 just say, well, there's way too much EPO; we ought to cut
19 back like 30 percent before we bundle it in there? You
20 don't have that argument either.

21 DR. LAZARUS: This is not a financial argument;
22 it's a how to argument. You can't give IV iron and you

1 can't give IV Vitamin D to somebody that's at home. Unless
2 we figure out a way to do that medically, technically, it's
3 not payment. You can give me all the money you want. The
4 patient cannot give IV iron at home and they cannot give IV
5 Vitamin D at home.

6 DR. EGGERS: So what's the solution here? We
7 just eliminate home patients from the payment system?

8 DR. LAZARUS: Well, I thought that was the
9 question.

10 DR. EGGERS: Well, that's why I'm asking you.

11 DR. LAZARUS: They're much harder to do, and
12 that's why I'm asking are they going to be in the whole
13 group or are you suggesting they be done separately?

14 DR. EGGERS: I'm suggesting that we have one rate
15 for patients, that we mush it together somehow, and let the
16 facilities determine how to allocate resources and treat
17 their patients just like they do now.

18 DR. LAZARUS: Well, that will get more people on
19 PD probably.

20 CO-CHAIRMAN AUGUSTINE: Other comments? Nancy,
21 I'd like to hear from you?

22 MS. RAY: I think from MEDPAC's perspective we

1 recommended that the payment bundle be brought in and
2 efficient providers' cost should be adjusted for factors
3 that affect efficient providers' cost, including the
4 modality. I think when you think about setting the one
5 rate as Paul has suggested, clearly that's one approach,
6 and that is a rather substantial incentive payment if you
7 were to think of that as terms of pay-for-performance if
8 you're trying to promote home dialysis.

9 Another way to promote home dialysis is to set
10 the different payment rates based on efficient providers'
11 cost. I think Brady has pointed out that the case mix of
12 patient characteristics probably differ from the home
13 population to the in-center, and so that would again be a
14 reason to think about setting up two different payment
15 rates. But again, Brady's point, not that pay-for-
16 performance is a panacea, but I think when it's linked to
17 those measures where you really want to see improvement, it
18 should lead to improvements of quality, one being vascular
19 access, another one perhaps being here in home dialysis.
20 But you're potentially talking about -- and people can
21 correct me. But on a monthly basis there's about a \$600
22 difference between home patients and in-center patients. I

1 mean, that is a huge --

2 DR. EGGERS: \$600 in what?

3 MS. RAY: Per patient per month difference in the
4 broader bundle between in-center patients and home
5 patients.

6 CO-CHAIRMAN AUGUSTINE: This is specifically
7 PDHD.

8 DR. BURKART: Perhaps one way we can help
9 facilities be efficient and reward them for efficiency is
10 if you do have the same payment. Some patients will not be
11 able to go home and will cost more money; some people will
12 be able to go home. And if there's an incentive for people
13 to go home -- I'm approaching this from the system we live
14 in today, how we're paid today.

15 If there's an incentive for patients to go home,
16 then facilities will be rewarded for efficiency. So if
17 part of the bundling is it increases the amount of money
18 that is paid per treatment equivalent, whatever therapy
19 you're on, and it cost less to go home, that's part of the
20 incentive to get patients to go home.

21 I just have to add anecdotally, there is
22 restriction to care. We have patients that come from many

1 miles away to our unit because they cannot do PD or home
2 dialysis at the unit they're at; it's not offered at their
3 units. So we need to do something to change that.

4 MS. ROBINSON: We're in effect taking away a
5 therapy choice for patients by not including home
6 therapies, and I think that's wrong of us to even start
7 doing that. Studies are showing that home patients have
8 better outcomes, have less hospitalizations, require less
9 EPO. I mean, why would we want to stop promoting that?
10 Those patients who want to take it home have every right to
11 take dialysis home.

12 CO-CHAIRMAN RUBIN: We wouldn't be changing
13 current law at all.

14 MS. ROBINSON: No, but if you're going to do a
15 demonstration project that only shows one choice, where is
16 that going to lead us? I think that we have to have an
17 opportunity for choice. And then how are dialysis
18 facilities going to actually participate if they have a PD
19 program? They're not going to be able to participate or
20 their PD patients won't be able to, in the demonstration
21 project.

22 CO-CHAIRMAN RUBIN: Well, depending on how you

1 view the demonstration; we've heard both views. During the
2 day that's either a good thing or a bad thing. It's hard
3 to know. There's no question that if we want to incent
4 people to choose the home option, we can do what Paul did.
5 I might point out we tried that 22 years ago, and it was a
6 dismal failure.

7 DR. WISH: Bill raised the question in terms of
8 whether we're comparing apples to oranges in terms of
9 benchmarks for anemia and PD versus hemo patients. I have
10 the 2004 annual report of the CPM on my computer. It's not
11 been printed yet, but I have it. This is fourth quarter of
12 2003 data. Percentage of hemodialysis patients with
13 hemoglobin greater than 11 was 80 percent; PD patients with
14 hemoglobin greater than 11 was 82, so they're pretty close.

15 MS. GREENSPAN: I just wanted to ask about
16 efficient providers. Are those providers who need the
17 quality benchmarks? You would be very efficient
18 economically if you don't give any EPO or iron in terms of
19 a home-based.

20 MS. RAY: By efficiency, we mean low cost, high
21 quality. I just wanted to be clear. I'm not suggesting
22 that the demonstration included only in-center patients.

1 What I was suggesting is that there should be some
2 discussion of setting one payment based on the efficient
3 provider cost for in-center hemo, another one for PD, and
4 perhaps using pay-for-performance as a mechanism to incent
5 home dialysis.

6 Just picking up on something that you said, that
7 there have been studies that have shown that patient
8 satisfaction is better for home patients than in-center
9 patients, that could be something that is measured and that
10 is perhaps is linked to pay-for-performance, just as
11 something to think about.

12 CO-CHAIRMAN AUGUSTINE: Thank you for
13 summarizing my comments from earlier in a much better
14 fashion than I did. I think that we're going to need to
15 discuss more. I think it would be helpful, as Bob kind of
16 mentioned to Michigan, if you could come back to us with
17 some more detailed information on a potentially separate
18 payment for PD home patients, and bring that back to the
19 next meeting. Does that sound like a recommendation that
20 we are comfortable with?

21 DR. EGGERS: Unless you want this demonstration
22 to be an in-center hemodialysis demonstration only -- and

1 my guess is that Congress would kind of wonder why you're
2 doing that -- I would direct them to do exactly that, but
3 think about the incentive there. If we don't lump them
4 together -- like I said, I realize that the composite rate
5 didn't do what we were supposed to do. But if we set up
6 something right now with two payments, one of which is
7 going to be only 40 percent as great as the other one, we
8 certainly will be getting more incentive to home dialysis.

9 CO-CHAIRMAN AUGUSTINE: I just want to make sure
10 we're still clear. This board directs CMS, and then CMS
11 will direct contractors.

12 DR. EGGERS: I understand.

13 CO-CHAIRMAN AUGUSTINE: And that goes back to
14 Nancy's astute comment on P4P. You may pay them based on
15 efficient use of resources, but then try to incent based on
16 P4P. Of course, how you incent people to have patients on
17 PD, which is kind of a clinical criteria, is a difficult
18 thing that we'd need to tease out.

19 DR. EGGERS: Again, we can probably all agree
20 that we don't want to do something that disadvantages home
21 dialysis.

22 CO-CHAIRMAN AUGUSTINE: So the recommendation

1 stands, that we'd like to hear more about home therapies
2 from Michigan at our next meeting?

3 MR. BACHOFER: Okay.

4 CO-CHAIRMAN AUGUSTINE: Okay, that sounds good.

5 As far as the four remaining bundles, 1A through
6 1D, I don't think we're going to have the time today,
7 because we're almost near the end of this session, to pick
8 a particular bundle. But I do think we need to agree that
9 we need to move to a bundle, not necessarily choose which
10 one it is. This isn't going to be a demonstration where
11 we're going to have two or three options. I think we need
12 to agree that we're going to choose an option and go with
13 it, because administratively again, getting something in
14 the *Federal Register* in the next few months, and then
15 getting it operational by January 1st would be extremely
16 much more difficult if we have various options at hand.

17 DR. LAZARUS: I think to pick one of these
18 bundles without understanding what the quality outcomes are
19 going to be is very difficult. I really think you're going
20 to have to discuss the outcomes before you ask us to pick
21 one of these bundles.

22 CO-CHAIRMAN AUGUSTINE: Well, that was another

1 reason why I'm hesitant to choose a particular bundle
2 today, but rather just to say it would be good to agree to
3 just have one in the end. As I said earlier, all these
4 things impact each other. After we get through the pay-
5 for-performance and the case mix, we'll have a better idea
6 of which bundle would be appropriate because all these
7 impact each other. That's one reason why right now I just
8 want to have an understanding that isn't going to be a
9 multiple option demonstration; that we're going to come to
10 an agreement on one. After we do some more pay-for-
11 performance and discussion on case mix, then we will say
12 this is the one we're going to choose.

13 DR. EGGERS: I have a question for Mike. You
14 can't make a decision on which one of those four until you
15 know what the outcomes are. What outcomes can be given to
16 you to help you make your decision? What outcome are you
17 looking for here?

18 DR. LAZARUS: Well, I mean, I don't know what
19 other is out there. I'm still not sure what other is.

20 DR. EGGERS: About \$16.

21 DR. LAZARUS: I understand \$16. I'm not going to
22 vote on 1D unless I know what other is. You've got to tell

1 me what other is. If we're going to have albumin as an
2 outcome, I'm going to look for something in here that's
3 going to help me get albumin up because I don't see them in
4 there right now.

5 SPEAKER: Do you know how to get albumin up?

6 DR. LAZARUS: No, I sure don't.

7 SPEAKER: Tell us, we need to know that.

8 DR. LAZARUS: So you've really got to tell us
9 what it is that we've got to achieve before I can figure
10 out whether I want the extra three drugs, seven drugs in 1C
11 . If infection's not in here, why do I want to pay for a
12 bunch of antibiotics? So is infection rate in or out? Is
13 that going to be an outcome? Is it just anemia and KT over
14 V?

15 MR. BACHOFER: Does that turnaround, by the way?
16 Does it say that if you want to include infection drugs and
17 labs in the bundle, that you should have a quality measure
18 or a performance measure?

19 SPEAKER: Yes. Oh, yeah.

20 (Chorus of yes's)

21 CO-CHAIRMAN AUGUSTINE: Mike, you're helping make
22 my point. I like when I state things, and people then turn

1 around and make me look smarter.

2 Let me get back to my point. We are going to
3 talk about this in much more detail with the
4 pay-for-performance discussion, which will occur after a
5 break which we're going to take in just a minute. But I
6 would like to garner an understanding that we would go
7 with one option as opposed to more than one. I want us to
8 kind of be in agreement on that. I don't think more than
9 one is an option that we're going to be able to administer
10 in time to meet our statutory requirements.

11 Any opposed to going with just one option?

12 DR. WISH: Not at all. What I was going to say
13 is for 88 bucks a month, which is the difference between 1A
14 and 1D, you're going to have a lot more burden, in terms of
15 performance measures, to look at all those other things
16 that you're including for basically less than 3 percent of
17 the total cost. So I'm just wondering whether it's worth
18 it; that's the issue. The administrative burden of
19 developing all the payment-for-performance measures and the
20 data collection, everything, for the 88 bucks a month that
21 you're including in the bundle I'm not sure is worth it for
22 CMS.

1 CO-CHAIRMAN AUGUSTINE: There's the payment
2 perspective and then there's the quality perspective.
3 We're going to talk about this more this afternoon. That's
4 a good segue.

5 From my understanding, based on the nods at the
6 table, we're going to move down the path of having one
7 particular bundle, which we will discuss at further length
8 after our pay-for-performance and potentially even some
9 further feedback from our contractor later today. With
10 that said, we're going to adjourn for a break. Let's
11 reconvene at 3:05.

12 (Whereupon, there was a brief recess.)

13 CO-CHAIRMAN AUGUSTINE: One of the things I'd
14 like to do before we start really honing down on a
15 particular bundle is I'd like to have the presentation on
16 pay-for-performance occur. After that, we're going to
17 carve out some time. Henry's only going to take about
18 30 minutes for us to discuss and start debating particular
19 bundles in a little more detail.

20 Henry, if you could go ahead and do the
21 pay-for-performance piece, we'll go from there.

22 MR. BACHOFER: Okay. The purpose of this

1 presentation is just to sort of help frame some of the
2 questions that need to be addressed if we are to include a
3 pay-for-performance component of the demonstration. Pay-
4 for-performance, as you probably are aware, is a major
5 priority for the administrator of CMS today, who is very
6 interested in promoting that. It is our belief that it
7 will be desirable to create or construct some kind of
8 pay-for-performance element of this demonstration. In
9 addition, as we've been discussing up to this point in
10 time, there are a number of issues that appear to be
11 conducive, if you will, or goals that could be pursued
12 perhaps through a pay-for-performance component rather than
13 trying to do it strictly through the sort of mechanism of
14 bundling services into the payment mechanism.

15 So my purpose today is really to begin laying out
16 the sort of questions, issues, that will be on the table to
17 provide s some guidance as we go out of this meeting and
18 begin structuring an actual solicitation that we would come
19 back to a structure for what the demo would look like in
20 the next meeting. I would urge people not to expect that I
21 am going to unveil a magic set of the perfect criteria or
22 goals that would go into a pay-for-performance thing, but I

1 will touch on what some possible quality measures might be,
2 but only in the most rudimentary terms.

3 First of all, just a point of orientation. The
4 purpose of pay-for-performance and quality incentives is a
5 fundamental break really with traditional thinking. The
6 characterization that I would give to it is that the goal
7 of P4P is to allow outcome, what is done for a patient, to
8 begin to influence payment to the facility rather than
9 having payment to the facility or provider be determined
10 entirely by what is done to the patient. It's a little bit
11 too neat perhaps a formulation but I think useful one.

12 CMS has generally defined the goal of its own P4P
13 strategy, which is still evolving -- it's very much a work
14 in progress -- as promoting the right care for the right
15 patient every time. And following the lead of IOM, we have
16 adopted generally the same framework that they adopted in
17 the quality chasm approach for thinking about the kinds of
18 measures that we might include; what are measures of
19 safety, effectiveness, patient centeredness, timeliness,
20 efficiency and equitability. Basically, those are also the
21 kinds of things we would like to promote as progress along
22 each of those dimensions.

1 What is the relationship between P4P and bundled
2 payment? We've already seen sort of an issue that has a
3 lot of different components, a lot of dimensions, it's very
4 large, and it's very complex. A significant question in my
5 mind is in a sense, are we talking about grafting a P4P
6 component onto the bundled payment demo, or are we talking
7 about sort of using P4P as an integral part of that bundled
8 payment demo to sort of support the overall or the same or
9 similar objectives that the bundled payment has? I think
10 in some ways the notion of bundled payment can be seen as a
11 kind of P4P. It's an attempt to create incentives for
12 those providers who are more efficiently able to meet the
13 needs of their patients for service, which is one of the
14 primary goals that I think a P4P system would have. It's
15 promoting efficiency, effectiveness, timeliness of care,
16 and so on. And to the extent that improvements along those
17 dimensions result in lower costs for the facility, then by
18 virtue of having a fixed-payment amount, they are in effect
19 being rewarded for those efforts. That essentially a kind
20 of P4P notion that is inherent in the basic notion of
21 bundled payment, or prospective payment, more generally.

22 In general, it is kind of a matter of

1 perspective. The questions that we'll be really looking at
2 are how can P4P support the bundled payment demonstration
3 either by dealing with issues that bundled payment, as
4 we've defined it, do not address, or by dealing with issues
5 that bundled payment may create?

6 That's so much for certainly a policy perspective
7 on it. At a technical level, there are about six questions
8 that you inevitably run into on this that need to be
9 address in designing a P4P system. The first of those is
10 simply what are the P4P incentives for. We've already had
11 some discussion of that. Are you paying for management of
12 infection, are you paying for management of vascular
13 access? What exactly is it that you're trying to pay for
14 through these P4P incentives?

15 How should the P4P incentives be funded? Where
16 does the money come from to pay for it? Generally, P4P
17 incentives come out of some kind of savings that are
18 projected due to increased efficiency, but we can come back
19 to that, and we'll discuss that in a little more depth in a
20 minute. There's a specific technical question about very
21 well and good in theory, but where does it come from when
22 we actually try to come up with the money to write the

1 checks against.

2 Thirdly, how large do the P4P incentives need to
3 be? Is moving 5 percent of the money around enough? Is
4 moving 1 percent of the money around enough? Do you have
5 to be moving more than that? Specifically, an important
6 question is, well, how big are the efforts, how much
7 effort, and what is the cost of the effort to achieve those
8 performance objectives? What does that cost look like and
9 how does that relate to the amount of money that's put on
10 the table in the form of the incentive payment? Asking
11 someone to achieve and improve in quality that might cost
12 \$10 per patient per month and offering to pay them \$5 per
13 patient per month is scarcely an incentive for them to do
14 it. That's the sort of notion there.

15 Fourthly, how should the P4P incentive be earned?
16 What is it that you have to do in order to earn it? I'll
17 come back and talk about that in a little more depth.
18 Fifth, what performance measures will be used? Again,
19 we've touched on that and we'll round it out and then come
20 back to that. And finally, whose performance is going to
21 be measured? Is it the performance of the facility or is
22 it some larger group?

1 MR. CANTOR: How will the components be measured?

2 MR. BACHOFER: That sort of cuts across a number
3 of issues; how is the P4P incentive payment earned and what
4 performance measures are you going to use for P4P? I think
5 you'll see how those two dimensions interact with one
6 another in a second.

7 The first question then is, what are the P4P
8 incentives for? One approach or one way of thinking about
9 this is to say, well, what we want to do is use P4P to
10 support the bundled payment itself, the purposes of the
11 bundled payment demonstration.

12 PPS creates incentives to improve efficiency.
13 P4P in contrast creates explicit incentives to improve
14 quality. So the question is, can we use some of those
15 measures to support, if you will, the overall purposes of
16 bundled payment, which was to create more effective and
17 more efficient meeting of the needs of dialysis patients.
18 Measures that you might include in this area would be
19 measures of adequacy of renal replacement therapy,
20 effective management of comorbidities and so on.

21 On the other hand, you could also reach beyond
22 the bundle of services that are included for P4P and not

1 just look at the question of how well are you dialyzing
2 patients and so on or how effectively, but to say we want
3 to touch on other issues that may in a causal way
4 contribute to that, but that are somewhat more loosely
5 connected with the underlying purposes, if you will, of the
6 resources that are being paid for through P4P. Those might
7 include management of vascular access, coordinating care
8 for underlying diseases, encouraging appropriate modalities
9 as we just talked about in this last section and the choice
10 between PD and HD; how could we use the P4P component to do
11 that; is that something that comes explicitly through a
12 bundled payment, or how do you even perhaps encourage
13 appropriate use of inpatient care? So there are various
14 questions there as to the payment incentives that we're
15 trying to construct here, what purposes are those related
16 to.

17 I think the tail end of the last discussion, I
18 think, Dr. Lazarus, you were saying, what are the quality
19 incentives I have, and that will sort of drive what's in
20 the bundle and my question of, well, what's in the bundle,
21 and that might drive what quality incentives I would want
22 to put in, are two ways of asking the same question, two

1 different perspectives on that. But the underlying
2 question is what are the incentives really to be used for
3 in some sense.

4 Secondly, how will they be funded? There are, as
5 I indicated, in any prospective payment system, implicit
6 efficiency incentives. If you can be more efficient in
7 your use of EPO, if you can be more efficient in your
8 ordering of lab tests, you will benefit from that, so there
9 are implicit incentives in having a fixed-price payment
10 system for that.

11 There also are implicitly incentives for
12 increasing effectiveness, provided the increase in
13 effectiveness is cost effective; does it increase your cost
14 by more than the amount of payment you have? There are
15 incentives for better management of complications in
16 comorbidity as both part of managing efficiency and
17 effectiveness and other dimensions that are mentioned in
18 the IOM report; safety, timeliness,
19 patient centeredness, and so on.

20 All of those improvements, if you will, in
21 quality are things that could be viewed as implicitly
22 funded out of savings that a dialysis facility is able to

1 achieve, given the bundled payment amount, or the
2 difference between what it cost them to provide those
3 bundled payment services and what they're actually being
4 paid.

5 However, it is also possible to create explicit
6 quality improvement incentives. That would require
7 additional funding of some sort. There are two basic ways
8 of thinking about where that additional funding might come
9 from. One is external savings, if you will. Well,
10 obviously there's three actually. One is that you
11 appropriate more money and put that on the table. In this
12 demonstration context, Congress has not really appropriated
13 any additional money to be put on the table for P4P
14 components of a bundled payment demo, so that one is
15 somewhat off the table, I think, at this point.

16 Secondly, you could look for external savings.
17 What I mean by that is that if through the better
18 management of the care that the patient has and given the
19 incentives that are created, you might realize savings on
20 services that are not paid for through the bundled payment.
21 The best example of that, the clearest and most obvious, is
22 vascular access.

1 If by moving towards increased reliance on
2 fistula you can reduce the incidence of hospitalization, if
3 you get improvements in quality of care, fewer days per
4 thousand or whatever, there may be additional money that
5 would be arguably available to fund P4P incentives that
6 would be really what would cover the costs of doing those
7 things to increase the reliance on fistula or whatever it
8 is that your targeted quality improvement would be.

9 The third approach -- I put these in this order
10 obviously for a reason, for most desirable to least
11 desirable -- is a conventional approach. If you look at
12 many P4P programs around the country -- particularly here
13 I'm thinking about the California demonstration with the
14 Californian physicians -- is through a withhold, a set
15 aside, some removable of funds and then disbursement of
16 those funds based upon achievement of the quality targets.
17 That is of course also the way in which the P4P component
18 of the capitated ESRD disease management is being funded,
19 is through a withhold arrangement. Any of these are things
20 that we would need to think about as we go forward.

21 Secondly, how large would the incentives be?
22 The purpose of the incentive payment can be conceived of as

1 two ways. It can be seen as a source of operating
2 revenues, if you will. It's payment for doing the things
3 that we want you to do in order to achieve the improvements
4 in quality that we are hoping that you will achieve, or it
5 can be thought of as simply a bonus for an investment in
6 improved service. You may be earning the bonus payment,
7 but it's not intended to fully compensate you for doing
8 these other pieces.

9 The considerations that would involve sort of a
10 choice along this dimension are what is the cost of
11 improving quality and is that cost something that is
12 recoverable, if you will, through the implicit incentives
13 of the bundled payment demo, through the things that you
14 would be doing within the bundled payment demo, or is there
15 a need to sort of look beyond simply your ability to
16 generate those savings out of the bundle and do things in
17 addition to or extraneous to that that would require
18 additional funding? In any case, the real question here is
19 to look at what it is the cost of accomplishing the
20 improvement in quality would be, and then how much money
21 has to be put on the table to either motivate people to
22 pursue that improvement or enable people to pursue that

1 improvement by providing sufficient revenue.

2 There are a variety of ways of how do you earn
3 P4P incentives; basically four. Generic approaches could
4 be adopted, a absolute consensus-based standard. Some of
5 the KDOQI (phonetic) guidelines would fit under this
6 heading. We expect to see certain threshold values that
7 are actually achieved. You could have a competitive
8 standard based upon a norm for a group of providers.
9 Generally that has been used. You could have an
10 improvement standard, not so much what are you doing
11 relative to an absolute standard, but what is your
12 improvement over your own performance over the past. And
13 finally you could combine these in endlessly creative and
14 convoluted ways, as we've seen out of a number of P4P demos
15 around the country in both the public sector and the
16 private sector. In fact, again, the capitated ESRD disease
17 management demo does use a combination of both an absolute
18 standard and an improvement standard within it. So we're
19 trying to encourage people to improve their performance,
20 but also to meet some absolute threshold.

21 What sort of quality measures might be used?
22 Tom, I think that is one part of the answer to your

1 question; how do you go about measuring quality or
2 performance? One is through improvement and one is against
3 the specific standard.

4 What specific measures might you use? This is of
5 course an enormous area. Again, as I said, I would love to
6 think that I had a magic box here that we could reach into
7 and pull out the specific standards. The good news for us
8 is that because of the amount of work that has gone on in
9 the ESRD community, there are a lot of standards out there.
10 Whether those are suitable for adaptation or for use here
11 would be something that we would be looking to people
12 around this table to advise us on.

13 There are a number of possible measures that have
14 certainly frequently been posed or noted; adequacy of
15 therapy, the incidence of complications in comorbidity
16 issues around use of vascular access, the extent to which
17 you have affected the management of anemia, modality choice
18 itself could potentially be some kind of a quality measure
19 that you would want to adopt and so on and so forth.

20 I think this is where the discussion perhaps
21 should focus on what kinds of measures might people propose
22 that we include. And when we come back to you, if we go

1 down the path of a P4P component -- which I believe we will
2 obviously -- what kind of measures should we be looking at
3 or including in there. One part of that might be to think
4 a little bit about what kind of criteria would guide the
5 selection of those measures or which measures you would
6 include in the package.

7 Along that dimension, MEDPAC, in its recent
8 comments on pay-for-performance, has sort of identified
9 some basic performance measures. I don't want to speak for
10 MEDPAC. I know we will have an effective presentation if
11 I've got this wrong. But essentially in their most recent
12 report, I think MEDPAC identified four broad criteria; the
13 use of acceptable evidence-based measures. In other words,
14 whatever measures it is that you use have to be acceptable
15 to the industry or the professions of the people whose
16 performance you're measuring.

17 You have to be able to collect those without an
18 undue burden on the provider or on the Medicare program for
19 that matter. There has to be an acceptance of
20 risk-adjusted methods. If there is a belief that these
21 measures have to be risk adjusted and that there are
22 specific ways of risk adjusting them, then your measurement

1 should use those accepted risk-adjustment measures.

2 Finally, there should be a possibility of
3 improvement along each of the dimensions. You don't want
4 to pick simply measures that people are already doing well
5 on. They should apply across a broad range of care. The
6 performance should be under the provider's control, not
7 under the extraneous events, which is really part of risk
8 adjustment. And it should focus on those areas that are
9 most in need of improvement.

10 With that as a very quick sort of overview of the
11 kinds of dimensions that we would need, the question then I
12 think comes down to. One is, what is the role of pay-for-
13 performance within the demo, how might it be used, and,
14 specifically, what kind of measures and methods of
15 measuring performance might we want to be incorporating
16 into whatever P4P proposal we come back to you with at our
17 next meeting?

18 CO-CHAIRMAN AUGUSTINE: Thank you, Henry.
19 Actually, that was a wonderful segue. As I stated earlier,
20 we kind of took a quick break to listen to P4P, and now I'd
21 like to kind of get back to us talking about --

22 CO-CHAIRMAN RUBIN: Before we do that, what do we

1 need from either the staff or does the staff need from us
2 in terms of instruction to get our arms around this P4P?
3 We have, in the course of the previous discussion, placed
4 what I think is a very large burden on the P4P mechanism to
5 make this thing fly. Henry has raised all of the right
6 issues in his paper, so somehow we've got to figure out how
7 it's going to be funded, how much money it is, and the
8 answers to some of the other questions.

9 I guess my question to either the group or to
10 staff is, what are the next steps? As you pointed out, we
11 need to get this done. We're going to have two days
12 together in July and I expect that we would say a P4P
13 proposal at that point in time. I just want to make sure
14 that everybody has the information that they need to do
15 that.

16 MR. BACHOFER: If I could actually start to
17 respond to that as I think about what we all have to do to
18 get ready for that next meeting or to draft something. At
19 potentially the risk of doing some violence to the
20 complexity of the issue, there's sort of two questions that
21 I think I have. One is sort of a very mundane question and
22 the other is sort of a bigger picture policy question.

1 The more mundane question is, where does the
2 money come from to pay for this? If there's going to be a
3 P4P component of this, how should it be funded? If you
4 look at the three options over here of additional funding,
5 external savings and withhold amounts, essentially it would
6 be useful to hear some discussion from people as to what
7 the relative acceptability of those various methods are.

8 If we're talking about bundled payment but
9 withholding a significant amount of it, is that something
10 that sort of says, no, we're not interested right up front,
11 or is there some interest in the possibility of using some
12 element of a withhold arrangement to help pay for or fund
13 P4P incentives, or are we looking at simply trying to make
14 the best case we can to then seek additional external
15 funding for this?

16 As you know, there is also of course the
17 proverbial 1. whatever it was percent that was provided in
18 this, but it is not our understanding at this point that
19 that was intended to be use necessarily for P4P, and in
20 effect that becomes a kind of a withhold if you were to
21 turn to that. So there's a variety of questions that are
22 simply related to this sort of the question of where the

1 money comes from.

2 CO-CHAIRMAN RUBIN: Just to throw in another
3 wrinkle, Jay Wish earlier today talked about the difference
4 between process measures and outcome measures.

5 MR. BACHOFER: Right.

6 CO-CHAIRMAN RUBIN: One might argue that to do
7 one, you have to make a certain kind of investment, and
8 that the fruits of those investments might be the outcomes.
9 So it's possible that there might need to be additional
10 funding for X and funding out a savings for the other type.
11 I guess what I'm saying is, we need intellectually to move
12 this forward in a time frame that I think makes sense.
13 Before we all depart this afternoon, I'd like to have some
14 understanding of what the committee can expect.

15 MR. BACHOFER: That actually gets me to the
16 second question, the bigger question. I have heard a fair
17 amount of positive, favorable discussions of P4P notions
18 around the table from the members of the committee. The
19 question that I would pose back is simply, what is it that
20 you would hope or would want a P4P component on this
21 demonstration to accomplish? What is it that it can
22 contribute to the demonstration of this larger bundled

1 payment? That's a little abstract. But in a sense if we
2 could leave this room with an idea of, oh, okay; what
3 people want is something that would be working. Whether
4 that's specific measures or types of -- I'm not entirely
5 sure at this point it's easy to hammer on vascular access.

6 CO-CHAIRMAN AUGUSTINE: Real quick I guess to
7 expound on something I said earlier, the role that P4P
8 plays here, if all we have to guard against unutilization
9 in an expanded bundled environment is the conditions, then
10 you could very easily see patient care kind of regress to
11 the means, so to speak the words, "patients hemoglobins are
12 between right and 11." Not to say people would provide
13 that care across the board, but there would be an incentive
14 to do so financially. The P4P would add an additional kind
15 of balance to unutilization to not just say that the
16 minimum is acceptable to us, but that we would like to
17 provide additional monies to those and recognize those that
18 provide the highest quality care. So it's an issue
19 regarding its unutilization and a recognition that people
20 are doing the best they can for patients.

21 One of the issues here is really trying to get
22 the payment system centered back on our beneficiaries. As

1 of right now, because of the payment system that we
2 administer, the incentive is to maximize separately
3 billables; it is not tied to patient outcomes. As a payor
4 we need to change that, and that's why we're here and why
5 we're working with you to try to figure out how to do that.

6 MR. CANTOR: I feel that if we start at the end
7 with payment, or what's the beginning of payment, the
8 amount of money, then we're not going to get traction. It
9 seems to me like the plastic's too soft here. By
10 principle, it sounds wonderful; pay-for-performance. Every
11 child should live in a happy home. It sounds great. But I
12 think we approach it from the standpoint of what are the
13 exact performances and ask two questions. First, if it
14 influenceable by the provider, and second, how important is
15 it because by its importance we can, in terms of the money,
16 influence whether it's going to be a necessity. In other
17 words, a facility has to have this extra money, so they
18 have to achieve this, or if it's going to be something
19 along the lines of a bonus.

20 But all those things only come out as you get
21 agreements on what are these exact performances, just like
22 we just covered vascular access. Otherwise, I think that's

1 what's happening in this room is that when we say pay-for-
2 performance, I have a feeling that everybody has in their
3 mind maybe a separate performance issue, which leads them
4 to take a position to either agree or disagree already in
5 their mind. That's why I was thinking that we could get
6 traction -- maybe, it's a suggestion -- by head on address
7 what are these performance issues, and then maybe it will
8 become clear for us as to how we proceed.

9 CO-CHAIRMAN RUBIN: I agree with that. What I'm
10 asking the staff is I don't want to be sitting here six
11 weeks from now and say, well, remember Tom Cantor said we
12 needed performance measures? Where are they? I want to be
13 very clear in our instructions that we need to see a plan,
14 and it may well be a matrix. It may be a bunch of
15 performance criteria, a bunch of funding criteria, and a
16 bunch of how you earn it criteria. And then we can sink
17 our teeth into something in a substantive kind of way.

18 CO-CHAIRMAN AUGUSTINE: We've got a good starting
19 point with Jay and all the work that CMS and Dr. Owen and
20 others have done with the CPMs. We've got a good starting
21 point for performance measures.

22 How they fit into the demo -- for example, in the

1 disease management demonstration we're actually capturing
2 the CPMs on a quarterly basis and making payments, from my
3 understanding, on a quarterly basis. That way they're more
4 timely, more actionable, and have a larger impact on
5 practice patterns. Recommendations and considerations such
6 as that would be helpful for us to have.

7 DR. LAZARUS: Two major things in all of your
8 plans, 1A through 1B, is the composite rate dialysis. The
9 major measure there is adequacy, so that seems to be a slam
10 dunk. The other is EPO, and the measure there is
11 hemoglobin. So it seems to me you have two measures that
12 you're going to have to put out. My only concern about
13 those two measures is that I think we're at the -- we're
14 not going to get any better. If we can stay where we are,
15 terrific. So if it's acceptable to have an outcome where
16 you can maintain where you are, I would suggest that
17 adequacy of hemoglobin are two that you have to put into
18 this, regardless of the plan we take.

19 CO-CHAIRMAN AUGUSTINE: They'll need to be in
20 there, but they're not as much an opportunity --

21 DR. LAZARUS: But your concern is that we're
22 going to gaming the system and drop off on both of those.

1 So I think they have to be there to make CMS happy that the
2 participants are not gaming the system.

3 CO-CHAIRMAN AUGUSTINE: Agreed. They are a
4 minimum; they are a starting point.

5 MS. GREENSPAN: If you made it so they were just
6 required in order to get your gain from the others but you
7 can't go back in those two, so that the gain, you'd list
8 your other criterion for a gain, and then say, but you only
9 get those if you didn't go back.

10 CO-CHAIRMAN AUGUSTINE: One of the things I
11 really would not like to neglect is minimum metabolism
12 because from my understanding -- that's an understanding of
13 how much that's a killer. It's harder to manage from my
14 understanding. But that's something that you could weigh a
15 lot better than I can.

16 DR. OWEN: Somebody's got to be gadfly here. I
17 want to return to Jay's comment earlier about process
18 measures versus outcome measures. First of all, I'm
19 reminded, what do we with renal replacement therapy when we
20 dialyze someone? We're doing chronic life support. There
21 are other components of health care where they actually use
22 outcome measures, which is to say they look at mortality.

1 I mean, all this stuff we're doing in terms of dialysis
2 dose, hemoglobin, et cetera, I mean, we're talking about
3 cost but we're dancing around what is a real issue here.
4 And that is we've got an awful mortality rate.

5 What has IDOP shown us? There is something that
6 is being done around the world that is influencing
7 mortality rate. So I'm going to be a real provocateur,
8 throw a glove down, and say why don't we reward somebody
9 for driving the mortality rate down? And I'm aware of the
10 issue of adverse patient selection, but at the end of the
11 day it's just like cardiac surgery. And that is who comes
12 out, and who's alive, and who's dead.

13 CO-CHAIRMAN AUGUSTINE: As a payor -- because I'm
14 purchasing care basically on our beneficiaries'
15 health -- we're interested in outcomes. We want to make
16 sure our beneficiaries receive the best care possible, and
17 that's our self-interest. As providers and as
18 practitioners, you control the process. We don't want to
19 really dictate process; our interest is really in outcomes
20 and leave it to you to figure out how to get the best
21 outcomes.

22 So to be fair to practitioners, we would need

1 some consideration for process indicators because that's
2 what they control, but there needs to be some consideration
3 for outcomes as well. And hopefully you choose processes
4 that are highly correlated with outcomes. Especially with
5 mortality, some ESDR are more highly predictive than
6 others. So some understanding of structure, process and
7 outcomes, all three of them may need to be considered for
8 this pay-for-performance.

9 DR. BURKART: One thing that we might look at, I
10 believe there's a paper about to be published that has
11 looked at what percentage of your patients meet all of the
12 criteria, and that outcome is related to meeting three out
13 of the five or four out of the five; not do 85 percent of
14 your patients have a hemoglobin above 11, but do 85 percent
15 of your patients meet five of these CPM indicators and that
16 actually survival is related to meet the number of those
17 indicators. That is something we could consider looking at
18 if in fact that data is true and is published.

19 DR. WISH: I don't disagree completely about the
20 importance of outcome measures, but I think until we get a
21 handle on adverse selection and cherry-picking, I think we
22 still have to go more towards process measures for the time

1 being because these are more clearly actionable. That's
2 clearly what the hospitals did, and I think it's working in
3 the hospitals. Almost all measures that the hospitals have
4 to report are process measures; did they treat the MI with
5 a beta blocker, did they treat the CHF with an ace
6 inhibitor, did they treat the patient with pneumonia within
7 four hours of the diagnosis? These are all process
8 measures, and the hospitals are paying attention and
9 they're working. I think the same thing can happen in
10 ESRD.

11 DR. OWEN: This group looks at hospital-based
12 mortality. They get rid of all that other crap. The
13 100,000 lives campaign is mortality. And there's a certain
14 amount of hubris that comes with I know what are the 8 or
15 10 things that you should focus upon. You don't know that.
16 We aggregate them and what do we have? Fifteen percent of
17 the variability in mortality. So how do I know my four are
18 necessarily better than your four?

19 Quite candidly, I'd say let the practitioner
20 decide what are the four, or five, or whatever, that are
21 important. At the end of the day as corny as it sounds, I
22 really do think it comes down to who's alive and who's dead

1 in that unit. I can drop the mortality in there, pat you
2 on the back, and then I'll come in afterwards and try to
3 learn what you do.

4 DR. WISH: But we have guidelines; these aren't
5 arbitrary. I mean, we have cardiovascular guidelines in
6 DOQI that say you've got to look at the lipids and you've
7 got to treat them with statins, and you've got to treat the
8 hypertension.

9 DR. OWEN: And show me that those have reduced
10 mortality. That's an expert panel that set around and
11 made, as you know, a plethora of assumptions. The data's
12 not there to support that those have changed mortality.
13 The ones that we do have mortality data on, we're sitting
14 here saying, geez, we don't like 8 percent; it's too low in
15 terms of accounting for the variability. I aggregate the
16 ones that we've patted ourselves on the back on, and the
17 best I can get is 16 percent.

18 So there's something out there, the preponderance
19 of stuff that is out there, that is influencing mortality
20 we're not smart enough to pick up on. Maybe use this truly
21 as an alpha test to try to find out what there is because
22 there are differences in mortality.

1 DR. WISH: Well, if you're going to just look at
2 mortality, who's going to take the patients that are half
3 dead when they get to your door, the patients with HIV, the
4 patients with severe cardiovascular disease?

5 DR. OWEN: Show me that that has occurred. We
6 talk about it and we talk about it. I remember in the RPA
7 we sat up there and said it was occurring, and then asked
8 for the data and couldn't find it.

9 DR. WISH: It's not happening yet because we're
10 not being paid for it.

11 MS. GREENSPAN: But also just the interval it
12 takes to reward the accomplishment of the outcome, it takes
13 too long to get the mortality to be able to see it because
14 there's too much intermittent that makes your risk very
15 high.

16 DR. OWEN: Fifty percent of my mortality for an
17 incident patient occurs at 30 months. That's pretty fast.

18 MS. GREENSPAN: But if you're going to do
19 quarterly rewards, the change in the departure from the
20 expected mortality to the actual mortality rate, how can
21 you do that so quick?

22 DR. OWEN: I didn't know we had decided on a

1 frequency reward.

2 MS. GREENSPAN: I mean, you're talking about
3 something like that. If you are not talking about doing a
4 three-year reward, how are you going to do that?

5 SPEAKER: Rate of infection. Is that less
6 controversial? Is that more influenceable by the provider?

7 CO-CHAIRMAN AUGUSTINE: I think we've heard
8 already kind of some general consensus that infection rate
9 is definitely something we need to keep track of. I don't
10 think we've decided any particular aspects of the pay-for-
11 performance, but infection would definitely be up there
12 with any others, as we start hauling it down.

13 Other comments on P4P?

14 DR. LAZARUS: I want to address the funding
15 mechanisms. Is that not part of the P4P?

16 CO-CHAIRMAN AUGUSTINE: No. Jay, one of the
17 reasons why outcomes are very important is because outcomes
18 are measurable financially. For example, hospitalizations.
19 If there's any chance that there's going to be a payment
20 above and beyond, which is an uphill battle to begin with
21 OMB, there would have to be a case made that better access
22 management reduces hospitalizations.

1 I do know that ASN brought this up to the
2 administrator last week and we had a discussion. He is not
3 adverse to considering the shifting of money between A and
4 B. It's not something that's exactly a barrier as has been
5 made out in the past, but there has to be a good case, a
6 good business case made. What would be helpful is to have
7 outcomes like hospitalization included in your P4Ps. You
8 know that the savings in Part A are at least paying for any
9 additional bonuses on the Part B side.

10 DR. WISH: I'm not saying you can't measure it;
11 in fact, you should measure it. I'm not saying you can't
12 report it, and you should report it. But I'm just saying
13 in your initial round of selection of criteria for P4P, I
14 think you should be more weighted towards process measures
15 because you're going to get buy in. This is stuff that's
16 actionable. This is stuff that can be done at the facility
17 level and the provider level. People can put their arms
18 around it and say, yes, I can do that. You tell them I
19 want you to reduce mortality, and they're going to say, I
20 can't do that.

21 CO-CHAIRMAN AUGUSTINE: Well, most measures we
22 have out there are process measures, like from the National

1 Kidney Foundation, KDOQI. They're mostly process measures.
2 For every four or five process measures, you're going to
3 need a mortality, you're going to need a caps instrument.
4 You're going to need something that's more outcomes patient
5 centered, but I think there's a good balance that can be
6 found between those, that if you have a good P4P system.

7 Other comments on P4P?

8 DR. LAZARUS: The three choices we had was
9 external choices, which Brady just addressed, which I think
10 is the only option, because withhold to me is not a
11 tolerable choice. If we have 500 facilities in this
12 demonstration, half of them are going to have improved
13 results and half are not. The half that are not are going
14 to fund the other half with a withhold, which means the bad
15 clinics, the poor clinics, are going to get less
16 reimbursement, and I don't see that as a viable way to
17 improve. You can't take the poor facilities and take the
18 money to pay the good facilities. I don't see that as a
19 workable solution.

20 CO-CHAIRMAN AUGUSTINE: I agree with your point,
21 but I will also add, that's assuming there is no
22 efficiencies driven into the system.

1 DR. LAZARUS: There are no efficiencies that we
2 can do with any of these things that I see that will reduce
3 my cost. I'm going to reduce cost of hospitalization. I
4 challenge anybody around this table to tell me where a
5 dialysis unit is going to save money with implementing any
6 of these things, except for reduced hospitalization. We're
7 not going to create any efficiencies in the units, I don't
8 think.

9 MR. BACHOFER: I think this is within the
10 congressional mandate. The expectation that there can be
11 increased efficiency in the use of injectable drugs is more
12 of a -- than anything else.

13 DR. LAZARUS: Well, I mean, given more EPO,
14 explain to me where the dialysis unit benefits from giving
15 more EPO --

16 MR. BACHOFER: Not giving more, giving less. In
17 other words, the savings that they would achieve would be
18 increased efficiency in the use of these inputs.

19 DR. LAZARUS: Well, if the goal is 80 percent of
20 people with a hemoglobin above 11 -- and we're all there,
21 struggling working to get there -- I assume most people
22 give adequate iron, or the physicians that are willing to

1 give iron, give iron. With a reduction in EPO dose, more
2 efficiency is going to drop that percentage of patients
3 down below 11, so back to the goal of -- I don't see a lot
4 of efficiencies here.

5 CO-CHAIRMAN AUGUSTINE: I wouldn't say that more
6 work less, and I wouldn't single out Epogen. I think that
7 it's more than the fee-for-service environment. There is
8 an incentive there on the side of caution that potentially
9 provide too much. We don't know how much and we believe
10 there may be some savings for more efficient use.

11 DR. LAZARUS: If you look at the
12 distribution -- I hate to beat this to death -- the
13 distribution gets 80 percent of the people above 11. That
14 largest percentage of people that looks to be too high is a
15 normal, physiologic distribution that's not going to go
16 away. I don't care what you do; that's not going to go
17 away. If you want 80 percent of the people to be above 11,
18 you're going to have 30 percent of the people above 13. I
19 don't care what you do; you can't change that. That's not
20 going to change. If you give me that bottom goal, look to
21 the distribution to tell you where everybody else is going
22 to be.

1 CO-CHAIRMAN AUGUSTINE: I don't disagree with the
2 distribution. You and I have had this discussion, and I
3 think it's pretty well known from almost everyone on this
4 board. I think one of the concerns is, for those patients
5 that are very low and stay very low -- that are getting
6 significant amounts of separately billable -- there may be
7 different care practices that will provide the same
8 outcomes with a lot lower costs.

9 DR. LAZARUS: We're back to transfusions, and is
10 that an acceptable practice in this demonstration. If I
11 get to 90,000 units of EPO for a week in a patient, that it
12 would be good medical practice for me to give them a
13 transfusion rather than more EPO. If this demonstration's
14 going to say that, then that's an opportunity. But there
15 are a lot of people out there that are going to argue and
16 look down on this demonstration if we do that.

17 CO-CHAIRMAN AUGUSTINE: I think that's a clinical
18 decision to make. I do think, including the blood
19 components into a bundle -- if we're going to include
20 anemia management or EPO, we need to include the blood
21 components in there as well.

22 Other comments?

1 DR. BURKART: When we're coming up with whatever
2 the measurements are going to be, is there a way that we
3 can get around the following problem? For instance, if we
4 pick, as a process measure or an outcome, a percentage of
5 patients at a certain level -- and some units are already
6 there and some units are not -- the ones that are not can
7 improve and can get there; the ones that are already there
8 can't. Is there something that we can pick that's apropos
9 for all units or do we have to pick different things
10 depending on the unit's starting point?

11 CO-CHAIRMAN AUGUSTINE: You say that MEDPAC has
12 actually provided some sound leadership here. Personally I
13 would like there to be an incentive to improve the care for
14 every patient, not only facilities that can reach a
15 benchmark, but also for those facilities who have a large
16 opportunity for improvement. In our previous disease
17 management demonstration, we paid not only for attainment
18 of thresholds but for percent improvement. That's
19 something I think this board should evaluate and consider
20 for this demonstration as well because that gives every
21 facility an incentive to improve.

22 Let's move back to the actual bundle composition.

1 I want the P4Ps to roll around a little bit, and we're
2 going to talk about that again. But first off, I'd like to
3 get back to the actual bundle composition.

4 One thing Dr. Wish stated earlier is that if we
5 get most of the way with 1A from a financial standpoint, is
6 it easier for CMS to go with 1A? From a financial
7 standpoint, yes, but one of the things that's good about a
8 bundle is it's easier for us to administer. For example,
9 1D actually gets rid of the 50/50 rule. The 50/50 rule is
10 a big pain for just about everyone, and it's very difficult
11 to administer. There are trade offs here between 1A and
12 1D.

13 After the last meeting, when Dr. Lazarus said
14 other practitioners send the patients in here to get blood
15 draws from the facility, that started making me think about
16 vascular access. I know we talked about this earlier.
17 Personally, as long as they're professionally competent to
18 draw blood in the facilities, which I believe they are
19 better than just about any other place, I would like the
20 blood draws for other outpatient facilities to be done in a
21 dialysis facility. I would like all the labs to be done
22 there. Number one, you will know who's sticking your

1 patients' arms, and, number two, have a better ability to
2 manage the access. I don't have a problem with that, and
3 that moves towards 1D as well.

4 DR. WISH: No, that moves towards a smaller
5 bundle.

6 CO-CHAIRMAN AUGUSTINE: Well, that would include
7 all outpatient labs.

8 DR. WISH: I want all these tests that everybody
9 else wants.

10 CO-CHAIRMAN AUGUSTINE: That would be 1D. That
11 would include all labs. All labs would come through the
12 bundled payment to the facility.

13 DR. WISH: Right. But then you're putting the
14 dialysis unit at risk financially for all these other tests
15 that everybody else wants. I think that's an disincentive
16 for 1D.

17 CO-CHAIRMAN AUGUSTINE: We want the patient to be
18 managed better. Right now, the patient shouldn't really be
19 getting blood drawn at a lot of different facilities
20 anyway. There should be kind of an understood message.

21 DR. WISH: Right, but there's a financial
22 disincentive for the dialysis units who accept all these

1 blood draws if they're not getting paid for it.

2 CO-CHAIRMAN AUGUSTINE: Those monies or those
3 other outpatient settings could be put into the bundle so
4 that facilities are getting paid for those other outpatient
5 labs, which are included in these analyses. So they're
6 getting paid for those labs, and their job would be to kind
7 of coordinate and ensure that patients get their blood
8 drawn from the facility and not get it done from other
9 locations because they could be liable for those costs if
10 they occur in another outpatient facility or location.

11 MS. CUELLAR: You're talking about blood draws
12 versus the lab --

13 CO-CHAIRMAN AUGUSTINE: Excuse me; the test, the
14 actual test.

15 MS. CUELLAR: Right. But then who's responsible
16 for that test? Is it the facility and the physician that's
17 in the unit then responsible for the results of that test?

18 CO-CHAIRMAN AUGUSTINE: If it's in the bundle,
19 the actual payment for the test would be in the expanded
20 bundle.

21 MS. CUELLAR: But there's a difference between
22 who's sticking the arm and who's monitoring that lab

1 result.

2 CO-CHAIRMAN AUGUSTINE: Who's sticking the arm,
3 who's running the test, and who's monitoring the result?
4 In the situation Mike described, it it's done before
5 another practitioner who's not credentialed at the
6 facility, they write a script and they come into the
7 facility, and the blood's drawn. It goes to the facility's
8 lab, is returned, and they would send the consult back to
9 the originating doctor.

10 MS. CUELLAR: So who tells the patient the
11 results in that scenario?

12 CO-CHAIRMAN AUGUSTINE: Excuse me?

13 MS. CUELLAR: Who gives the patient the results
14 in that scenario?

15 CO-CHAIRMAN AUGUSTINE: The person that ordered
16 it I guess is the person who wanted it. They should be the
17 one to share it with the patient.

18 DR. LAZARUS: That's a medical question that
19 you're asking. Who is legally, morally responsible for a
20 bad test that comes back? The dialysis unit has a bad
21 test, and this doctor outside who asks for the test doesn't
22 pick up on it. The patient has some contractible disease

1 and dies. I'm stretching here. But who's responsible now
2 that it's on our table? We got paid for it; we drew it.
3 Who's responsible for it?

4 CO-CHAIRMAN AUGUSTINE: When someone refers a
5 patient and they get their blood drawn at your facility
6 today and you run it, and you write the consult, back,
7 that's no difference than today.

8 DR. WISH: If it's a separately billable test
9 today, then you get paid for it.

10 CO-CHAIRMAN AUGUSTINE: It's the same situation.
11 You're still getting paid, and you're running the test, and
12 you're getting the result, and you're sending it back to
13 the originating doctor. The payment issue is no different.
14 You're still getting paid today just as you are in an
15 expanded bundle for the same test. So there's no new
16 issues that we don't already have.

17 DR. WISH: But I think that expanding the bundle
18 to include all of those tests that come from the outside
19 world is actually a disincentive for the dialysis unit
20 doing it. I think if they're separately billable that's
21 more of an incentive for the dialysis unit to want to take
22 those patients and do those tests, not less an incentive.

1 CO-CHAIRMAN AUGUSTINE: Well, if they can be an
2 efficient provider and work with their beneficiaries to be
3 sure that they get their blood drawn at the facility during
4 their session, it's an economic incentives because there
5 are monies out there that are included for other
6 practitioners; that if that goes away and the blood is
7 drawn all at one time as opposed to being drawn at two or
8 three places, then there's an economic incentive for a
9 facility.

10 MR. BACHOFER: The economic incentive, though,
11 Brady, actually has two sides to it. There's the incentive
12 that the facility is operating under and then there is the
13 incentive that other providers are operating under. And in
14 a bundled payment system all of those other providers would
15 have an incentive to not provide the tests themselves and
16 instead refer to the dialysis facility, because if they
17 submit the claim, they aren't going to get paid for it.

18 CO-CHAIRMAN AUGUSTINE: It's an efficiency in the
19 sense that instead you're getting your blood drawn as fewer
20 times as possible.

21 DR. WISH: Well, I don't think all those other
22 providers own their own labs and bill for these tests.

1 MR. BACHOFER: I agree, but just in terms of the
2 incentive structure, there certainly would be. If you
3 bundle the lab work into the facilities payment, the
4 facility has an incentive to reduce utilization of
5 laboratory services and so not to take on the task of doing
6 all of those tests for other entities. But if those other
7 entities can't handle lab tests paid for, except by having
8 it done through the facility, then they would be -- if I
9 could use a term that I hesitate to, it's a more coercive
10 approach because it forces the test back into the facility
11 so that the facility has to bill it.

12 DR. WISH: I hope I'm not usurping everybody
13 else's raising their hand. Just to make a
14 counter-argument, I think what's more important is to
15 educate all these other doctors not to stick these
16 patients' arms. I think what's going to happen is they're
17 going to still stick the arms because the patient's there
18 in their office, and they send them to their local lab, and
19 they'll send the specimen to the local lab, which then
20 won't get paid. And they won't run the test, and the
21 patient will have got stuck anyway.

22 DR. OWEN: I guess this question is directed more

1 toward Dr. Wish and Lazarus. I'm reminded that maybe 5 to
2 10 years ago you gentlemen developed a position paper for
3 the RPA that dealt with the issue of whether or not the
4 nephrologist was a subspecialist who triaged, or whether or
5 not the dialytic nephrologist was kind of the primary care
6 physician for a patient with ESRD. I'm also under the
7 impression that the organization with strong support from
8 the community landed on that the nephrologist was a primary
9 care physician for a patient for ESRD.

10 If I look at that chart, the amount of difference
11 in money is not a lot. I know when I multiply it out, as
12 we talked about, it's a lot. So I'm saying, well, if I'm
13 not spending a whole lot of difference on the money, are
14 there substantial differences in terms of those IOM
15 maximums that we have on the board?

16 So if the nephrologist is kind of the primary
17 care physician for a person, is there a certain amount of
18 enhanced coordination, safety and effectiveness that's
19 offered by having everything go through you as the
20 nephrologist with things being bundled? At the end of the
21 day it's not a financial issue. It quite honestly is one
22 of actually your legal accountability.

1 DR. LAZARUS: That was a debate back then. I was
2 on the pro side of the physician did everything, but that's
3 not what happens in this country today. Unfortunately,
4 there are many nephrologists that say I take care of the
5 dialysis and that's all I do. What happened 20 years ago
6 in the debate is a far cry from what's really happening.

7 DR. OWEN: I guess I'm asking is this an
8 opportunity for us to drive that in that direction if
9 people think this is the right thing to do, or do you want
10 to have fragmented care providers? I think it was you who
11 posed the question. If that test is sent off under my
12 name, am I accountable for it?

13 I can tell you guys. I have a health system that
14 now does a lot of free care. Whether you're paid or not,
15 if your name is attached to that test, you have both a
16 moral and a legal obligation to follow up. So does this
17 give me now a bully pulpit? Does it also now make me the
18 person who can take coordinate that care because it's all
19 crossing my desk?

20 DR. WISH: Well, if you look at the continuum of
21 care from CKD on, I think one of the major barriers that we
22 all recognize in terms of timely referral is the perception

1 on the part of the PCP that the nephrologist is going to
2 steal their patient, so the last thing we want to do is
3 legitimize that into fiscal policy.

4 DR. OWEN: You saying a CKD patient. I thought
5 this was an ESRD patient we're talking about.

6 DR. WISH: Right, but most primary care
7 physicians still don't want to lose their patients to the
8 nephrologist even once they have ESRD.

9 DR. BURKART: We don't know if all the labs that
10 could be drawn on a patient are being drawn. Primary care
11 physicians can make money with ancillaries, just like the
12 dialysis units do, and so some of them want to do their
13 labs. We did bring up last time that the reason a lot of
14 these things are drawn is because the patient is on
15 dialysis, their arm is there; let's do it.

16 I think that we should facilitate being able to
17 have the labs drawn at the unit because they have ready
18 access to the blood, but I don't know that that means that
19 it needs to be part of the composite rate. I think that it
20 should be that the patients can have the labs drawn there
21 and it's a separately billable thing, and if the primary
22 care doctor orders the lab, and your unit will allow it to

1 be drawn under the primary care doctor's name, we've got to
2 do it that way.

3 CO-CHAIRMAN AUGUSTINE: I hate to admit this, but
4 the payment system is much more a strong driver than you
5 may give it credit for. If it is in the payment system, it
6 may happen for a little while, but it won't happen for
7 long. There are not many practitioners, or businesses, or
8 people in this world that run their business to lose money.

9 DR. BURKART: No, no. If they can't do it
10 anymore, they won't. But at the moment they probably want
11 to have some labs draw it.

12 CO-CHAIRMAN AUGUSTINE: It's been 10, 20 years
13 and we have all the best interest in the world, but it's
14 not happening. This system is broken, and just by hoping
15 that it will get better will not make it better. We've got
16 to start making changes structurally to the system, and
17 until we do so -- what's the old dimming maximum; if you do
18 the same thing 10 times and it doesn't work, the 11th time
19 you'll get the same exact response; something like that.

20 DR. WISH: Albert Einstein says "the definition
21 of insanity is doing the same thing over and over again and
22 expecting a different result."

1 CO-CHAIRMAN AUGUSTINE: I love to air my
2 misquotes to the public.

3 DR. LAZARUS: I get the impression that at least
4 you, and maybe Bob, are pushing 1D. Is that my
5 interpretation of what I'm hearing?

6 CO-CHAIRMAN AUGUSTINE: I'm not pushing. I'm
7 just saying without having consideration for transfusions
8 and the lab work -- I mean, this is an opportunity for us
9 to try to infuse some better coordination of care. And if
10 we just include the few drugs, then we're not going to be
11 much different than where we are today. All of a sudden
12 you'll see quarantine or all of a sudden you'll see other
13 separately billables skyrocket because that's the financial
14 incentive that the payment systems sends.

15 So instead of focusing on these separately
16 billables, we're just going to focus on other separately
17 billables. I think if we're going to move this payment
18 system to be patient centered, then we need to forget about
19 separately billables and start focusing on outcomes. Pay a
20 fair rate for a fair day's work, as the old saying goes,
21 and then try to incentivize the outcomes instead of
22 incentivizing the processes. That's what we're trying to

1 get at here, and that's why I think D is helpful.

2 CO-CHAIRMAN RUBIN: Could I make a suggestion? I
3 notice we're into the public comment time, and maybe to
4 facilitate this.

5 You asked me where I was. I don't know enough to
6 know which I'm for because what I want to see is what we
7 haven't yet seen. That is to say, what's the variation at
8 the facility level. I want the people from Michigan to go
9 back and dig into A, B, C and D, and look at what that
10 variation is and how we can deal with that with case-mix
11 adjustment, and see whether it makes practical sense to be
12 more inclusive or less inclusive.

13 A lot of people have been throwing around, well,
14 it's 5 bucks, and 5 bucks there, and \$16 there. It begins
15 to add up to real money. I don't want us to make a
16 recommendation that the agency follows and then throws a
17 party that nobody shows up to.

18 Right now, what I would like to see and what I'd
19 like to hear again from the staff is whether they can do
20 the kinds of analyses that were in each of their next-step
21 slides on A, B, C and D, and come back in July, look at it,
22 talk about it, and see what makes the most sense. But

1 right now what we saw is we've got huge variations. We
2 have R²s that are low. Now, whether they can be made
3 better, who knows. Let's try to put some meat on the bones
4 of what we've already seen.

5 DR. LAZARUS: But the only variation that really
6 matters, Bob, is EPO. Everything else fails in comparison.
7 So the variation there is EPO dose, and the rest of them
8 vary within the clinical parameters. So why would you
9 waste time looking at everything else but EPO? I mean,
10 that's where the variation is.

11 CO-CHAIRMAN RUBIN: Well, we don't know that at
12 the margin, I don't think.

13 DR. LAZARUS: What do mean?

14 CO-CHAIRMAN RUBIN: Well, we don't know whether
15 the distribution of costs, among these other things, is
16 random or non-random.

17 DR. LAZARUS: I don't know what you mean.

18 CO-CHAIRMAN RUBIN: Are they all centered in
19 certain kinds of facilities, is the concentration uniformly
20 distributed, are there some characteristics that can more
21 adequately predict high costs in particular months? I
22 don't know that.

1 DR. LAZARUS: Yeah, the antibiotics are all
2 related to catheters. That's the other answer.

3 MS. GREENSPAN: One worrisome thing about
4 1D -- at least we know what's in 1A, 1B, 1C and if we agree
5 that, okay, we're willing to buy that risk. 1D could have
6 something that's an item in little use now that will become
7 in much greater use. So for 16 bucks you take a huge
8 amount of risk over 1C.

9 CO-CHAIRMAN AUGUSTINE: Do you expect certain med
10 surg supplies to all of a sudden grow geometrically?

11 MS. GREENSPAN: No, I don't think it was only med
12 surg supplies. That's what I mean. I think I'd want to
13 see everything that we're actually saying this is now
14 incorporated in that 16 bucks.

15 CO-CHAIRMAN AUGUSTINE: Well, blood would grow in
16 one area and EPO would go down in another area.

17 MS. GREENSPAN: It's risky.

18 MS. RAY: What is added in 1D that's not in 1C?
19 Is it just the med surg supplies?

20 MR. BACHOFER: Medical surgical supplies is the
21 largest item, followed by blood processing and storage,
22 followed by preventive services, which is about \$1 million

1 a year aggregate, followed by blood products and blood,
2 followed by radiology, diagnostic, EKG, ECG, cardiology,
3 respiratory services, clinic services, CT scanning, other
4 imaging, treatment, observation, nuclear medicine,
5 ambulatory surgery, MRI, OR, ER, pulmonary function. I
6 mean, many of these things are -- but they're tiny dollar
7 amounts.

8 Having said that, gone down that huge, long
9 list --

10 DR. BURKART: The things that are listed on
11 page 12, 13, 14, 15, 16, 17, 18, right?

12 MR. BACHOFER: Right. I think we included that.

13 MS. GREENSPAN: But you don't want to take the
14 risk for all those things for \$16 a month.

15 MR. BACHOFER: No, no, no. I would argue,
16 looking at this list, that if you go down it, what you
17 really see is that there are many things on here that you
18 wouldn't really probably want to bundle. Clearly, like
19 most of the imaging, for example, was probably patients who
20 are being referred to a hospital in all likelihood, because
21 most of these costs, incidentally, are in hospital-based
22 facilities. What that looks like is that the hospital-

1 based facility happens to have an ESRD patient that shows
2 up for imaging or whatever, and when they cut the bill at
3 the end of the month, they simply cut a 72X claim, even
4 though they weren't necessarily doing dialysis on the
5 patient, and submitting the claim, and so it comes through
6 on this.

7 My contention looking at this is we would have to
8 selectively say there's maybe three, four or five
9 big-ticket items, where there's real money attached to it.
10 And say those are the things that we would pull out of 1D
11 to include into it. Today we had some discussion of blood
12 and blood products. If we have EPO bundled in it just
13 occurred to me that then you create incentives to
14 substitute blood for EPO. So there's a clear substitution
15 margin that would be raised here.

16 So you would want to pull blood and blood
17 products, medical surgical supplies, and maybe one or two
18 other items off of this list. But the other things that
19 are smaller dollar amounts, like nuclear medicine, imaging,
20 OR, pulmonary function, emergency room and so on, those
21 would not be candidates for being bundled.

22 DR. EGGERS: Particularly if you had a system

1 that didn't allow anybody else to bill for that.

2 MR. BACHOFER: Correct.

3 DR. EGGERS: All of a sudden you have these
4 bizarre, weird small things cutting of access.

5 MR. BACHOFER: Right.

6 MS. RAY: It might be helpful for the panel, for
7 at least these 1D payments, if you could provide some sort
8 of time trend. The best of my recollection is that at
9 least for freestanding facilities, to look at payments in
10 2000, 2001, 2002, 2003 to give the panel a sense of whether
11 or not these payments have increased or decreased over time
12 and also to give the panel a sense of -- to the best of my
13 recollection, this really is less than 1 percent of all
14 facility payments.

15 MR. BACHOFER: That's correct.

16 MS. RAY: But I think it would be helpful to
17 provide that information to give some context.

18 MR. BACHOFER: Just a quick response to that.
19 These numbers are for 2003, and I had requested these
20 because the Phase 1 report that KECC did involved an
21 earlier year, 2002 if I recall correctly. These numbers
22 are very close in terms of their overall pattern. So just

1 a one-year trend is a one-year trend, but it doesn't show
2 very much change.

3 MS. RAY: Right. That's what I was going to say,
4 just for freestanding, but I haven't looked at these 1D
5 services for hospital base, but that was the best of my
6 recollection.

7 MR. BACHOFER: This for everyone.

8 MS. RAY: Right.

9 MR. BACHOFER: These are all claims.

10 DR. BURKART: All claims done no matter where
11 they were ordered.

12 MR. BACHOFER: No, these are dollar amounts that
13 appear on claims that are submitted by facilities, by any
14 facility, not just hospital-based facilities.

15 DR. BURKART: Because Bonnie's point is, let's
16 say you want to buy a TV and they happen to be in the
17 grocery store. Well, you don't go to the grocery store to
18 buy a TV; you go to wherever. And then all of a sudden if
19 you're told, you can only buy it at the grocery store, all
20 of a sudden it's going to go way up.

21 MR. BACHOFER: The list can be amended. There
22 are some things that may not need to be on there that can

1 be taken off. I mean, there more of anomalies. But some
2 of them like blood component technology, blood components
3 and what not, they surely would need to be in there.

4 CO-CHAIRMAN AUGUSTINE: Are there any members of
5 the board who'd really like to discuss some of the
6 intermediate bundles, the 1B and 1C? It sounds like we're
7 talking more about 1A and 1D.

8 MR. BACHOFER: What I would call 1A and 1C+.

9 DR. WISH: I understand where you're coming from
10 in terms of trying to close every loophole. I think as
11 long as there's the potential for separately billable items
12 that there will be behavioral offsets that will exploit
13 that, and I can understand why that is attractive to CMS.

14 My major concern again just has to do with the
15 data collection and the reporting infrastructure that's
16 going to be required to adequately monitor or reward,
17 punish, or whatever you want to talk about, all those
18 intermediate steps between 1A and 1D since they are very,
19 very small in terms of monetary value and yet potentially
20 very big in terms of administrative oversight.

21 MS. RAY: I just want to make a point. 1C
22 includes the Hepatitis B vaccine and the flu vaccine. I

1 remember looking at some earlier USRDS work that suggested
2 that the use of certain preventive services -- and I think
3 those were included -- was actually lower among ESRD
4 patients than among non-ESRD patients. So I think
5 including them in the broader bundle gives us the
6 opportunity to improve quality of care, particularly for
7 those two items.

8 SPEAKER: No, you just put in performance
9 measures for them. It's irrespective of whether or no
10 they're in the bundle.

11 CO-CHAIRMAN AUGUSTINE: Because if they're in the
12 bundle there's an incentive not to actually do them. You'd
13 have to have a performance measure to go along with them to
14 ensure that they occur.

15 MS. RAY: Well, in the bundle and measurements
16 together.

17 CO-CHAIRMAN AUGUSTINE: Agreed.

18 DR. OWEN: I just wanted to comment that, in
19 fact, if you look at time trend analysis for an individual
20 patient, it actually goes down as they go from CKD to ESRD,
21 which makes me return to my point; who's actually driving
22 the ship.

1 CO-CHAIRMAN AUGUSTINE: Every different bundle
2 that we evaluate, our contractors had to do that much more
3 work, and I'd like to actually focus it as much as
4 possible.

5 Is there a clear distinction to Bundles 1A and
6 1D, which is what I'm hearing, but I may not be hearing
7 correctly, those of you who preferred 1C, 1D.

8 MR. BACHOFER: Brady, if I could comment while
9 people ponder that issue.

10 I actually have to say, having lived with these
11 data far too intensively over the past two weeks, I
12 actually see relatively little analytic gain likely to come
13 out of detailed analyses of the individual bundles. In
14 other words, doing a comparative analyses of 1B to 1C is
15 not likely to turn up a whole lot of useful, terribly
16 insightful information. What we do know at this point in
17 time about those intermediate bundles is that they do
18 display a different pattern of utilization; that's true.

19 I think where we would learn something from is to
20 look at something that would be sort of a 1C+ or whatever
21 you want to call that, and then see what the sort of
22 detailed questions are that Bob identified about what is

1 the impact across facilities, what kinds of facilities
2 might be adversely affected, and so on. But then hold and
3 reserve the question -- in a sense to come back to
4 that -- of if you were to eliminate everything between 1A
5 and 1C and just go back down to 1C, where is that injury
6 occurring; where is the problem arising?

7 As Mike has indicate here, it really is EPO
8 that's driving this whole thing, this EPO variation, in a
9 sense. It's not just EPO; it's that set of three drugs
10 because I don't want to pick on any one category. So if
11 you back out everything other than that, is there still a
12 problem with what's left. That might be a more productive
13 avenue in terms of what we would learn from it, but to
14 really sort of focus on the broader bundle, and then ask do
15 we see problems there that would be fixed by moving to more
16 narrowly-defined bundle.

17 CO-CHAIRMAN AUGUSTINE: That's a good suggestion.
18 Anyone have any issues with that? Then we should follow
19 that.

20 DR. WOLFE: I just wanted to give a little more
21 context to the case-mix adjustment. I would echo Henry's
22 comment. One of the slides we showed compared the R^2 and

1 our ability to explain variation between two of the
2 bundles. There was some difference, but it wasn't all that
3 great.

4 There's been quite a bit of discussion about how
5 miserable these models are. Let me give a little bit
6 better context. On one of our slides -- page 18 of
7 Section G -- it shows no model compared to case-mix
8 adjusted. The unexplained patient variation went from \$48
9 down to \$43, which just doing the numbers is about a 15 to
10 20 percent R^2 at the patient level. We're never going to be
11 able to explain the month-to-month variation; that's just
12 pure error. And that's part of this calculation of what is
13 the hypothetical R^2 you can hope to get to.

14 We're not great, but we're not terrible either.
15 It's not nearly as terrible as 7 percent if you think of
16 explaining all the variation. But in terms of explaining
17 the important variation from patient to patient, we're
18 explaining close to 20 percent of the variation from
19 patient to patient with our current case-mix model. That
20 happens to be Bundle 1C, but it's not going to be a very
21 different story for these other bundles. If we put in
22 prior EPO use, we get a substantial bump up in that.

1 Please, don't let the case-mix number -- at least
2 not that particular number -- make you think, well, we're
3 never going to get there and never have any decent case-mix
4 adjustment. I think the interesting number to look at
5 really is the dollar unexplained variation and can you live
6 with that, and recognize that that's going to go down. As
7 you average cost patients at a facility, it's going to go
8 down rapidly. So the risk that you actually see in
9 unexplained variation from case mix, it's not negligible,
10 but it's also not the driving issue in this question I
11 think. I just wanted to give a little bit of context
12 there, and sorry for all the numbers.

13 CO-CHAIRMAN AUGUSTINE: Thanks, Bob. That's
14 actually quite helpful.

15 Now, we're going to move to our public comment
16 section. I know that we've had a lot of people patiently
17 waiting in the audience and would like to opine and provide
18 some input to the board as we deliberate. I'd like to open
19 up that opportunity now.

20 First of all, we've got Mr. Kenley from Aksys.

21 MR. KENLEY: Thank you, Brady.

22 My name is Rod Kenley. I'm employed by Aksys

1 Limited. We make an instrument for daily home
2 hemodialysis, so it shouldn't be any surprise that we are
3 very gratified to hear the discussion on the intent of this
4 body to incentivize home modalities of all kinds. That
5 certainly was our reason for supporting the expanded bundle
6 because we feel the expanded bundle will result in expanded
7 choices for the patient, choices that really haven't been
8 available to these patients for a long time now.

9 As I heard the discussion evolve, I heard two
10 proposals for how to incentivize home modalities, one being
11 what I came here today expecting to hear, that there would
12 be one rate for any way you want to do dialysis. That
13 would incentivize those modalities that have the lowest
14 costs. With that, if we have quality indicators and
15 outcome measures that are more easily reached with these
16 home modalities, that will further incentivize the use of
17 them.

18 I heard an alternate proposal that maybe we
19 should pay less for lower cost modalities. I would
20 strongly oppose that for the following reasons. We tried
21 that once and it didn't work.

22 When we put the reimbursement in place in 1973,

1 there were 42 percent of all patients on home hemodialysis.
2 That rapidly eroded to the point where in 1977-1978, there
3 was a lot of effort to reconfigure reimbursement to
4 reincentivize home modalities, including, most
5 particularly, home hemodialysis. There was a lot of debate
6 that went on, including a proposition that came close to
7 passing that would stipulate a minimum percentage of all
8 people that should be on home dialysis.

9 That didn't make it into the final rule. What
10 did make it was the maximum number of practical patients
11 should be put on home modalities, and 75 percent
12 reimbursement was applied to a home modality. What
13 happened? We continued to lose home patients at a rapid
14 rate until 1983 when the composite rate was initiated.

15 Dr. Rubin, you commented that you thought that
16 was a failure for home modalities. I respectfully
17 disagree. The growth of peritoneal dialysis throughout the
18 1980's could largely be attributable to that composite
19 rate, not entirely, but certainly there's a component. In
20 fact, I think the failure of the composite rate was the
21 lack of an annual update, such that by the time we got to
22 1990, plus or minus a year or two, Medicare patients became

1 unprofitable, resulting in the need to make the profit on
2 the separately billable injectables, and therefore keep the
3 patients preferentially in the centers, rather than letting
4 them go home. Well, now we're recognizing the fallacy of
5 that.

6 I'll give you another example of why I think
7 putting an upfront disincentive for home dialysis is the
8 wrong way to go, and I view this reduced rate as an upfront
9 disincentive.

10 We have also back in 1978 instituted a \$20
11 increment over the composite rate for training sessions for
12 that month or so when the home training patients are being
13 trained. That has never been increased. At least the
14 composite rate has been increased three or four times. Had
15 that been increased by the rate of medical products
16 inflation that would be \$110 right now.

17 I went to the cost reports and looked at all the
18 clinics that were reporting more than 100 home hemo
19 training sessions per year. On average, they are losing
20 \$4,680 for each patient they train for home hemo.
21 Secondly, they have to pay for the modifications to the
22 plumbing and electricity, another \$1,200 to \$1,500.

1 They're eating \$6,000 of negative cash flow to get a
2 patient at home right now.

3 Is it any wonder that we've got an almost
4 immeasurable percentage of patients on home hemo? In fact,
5 CMS doesn't have to wait for the implementation of an
6 expanded bundle to get rid of that disincentive. That
7 would cost \$1,125,000 to pay just the actual costs for the
8 training sessions for home hemo patients, according to the
9 total number that were trained last year. That's 1/100th
10 of a percent of the total ESRD budget. But I'm here to
11 tell you that's a major reason why a lot of clinics don't
12 do any home training, because when they eat that money up
13 front, they know that they can make it back, but only if
14 the patient lasts on that modality for about 18 to
15 24 months.

16 Well, with transplantation at 25 percent,
17 mortality rate, and other reasons for transferring back to
18 in-center hemo, there's a real risk that that patient won't
19 turn profitable until they have to come off of that home
20 modality, so why would people do that? They won't. If you
21 simply covered those upfront costs, they'd be a lot more
22 inclined to take that risk.

1 In terms of quality measures for our P4P, our
2 original promise to Congress in getting the '73
3 reimbursement law was rehabilitation. My perspective is,
4 whatever you're doing to that patient, if they are more
5 likely to be rehabilitated or have a higher level of
6 functioning, both of which are easily measurable,
7 everything else you're doing is probably good. So to me,
8 that and mortality, to support Dr. Owen's comment, are the
9 two ultimate quality measures that should make the final
10 cut. Hospitalization should as well. What should not make
11 the final cut is paying people to reach a KTOV review
12 that's determined for three-day-a-week dialysis. That's
13 prehistoric based on what we know now. If you're going to
14 use any quality measure for dose, it should at very minimum
15 be weekly standard KTOV. Thank you.

16 CO-CHAIRMAN AUGUSTINE: Thank you very much.
17 Leanne Zumwalt, you're up next from DaVita.

18 MS. ZUMWALT: I have some data that I'm going to
19 leave with you, but I wanted to make a few comments
20 regarding the challenges of implementing a bundle. First
21 of all, this ESRD population is quite different than a
22 typical Medicare population. You look at them

1 individually, they have changes in their cost structure
2 over time, they have different issues as they progress
3 through ESRD, and they are chronically ill.

4 In addition, the data presented today shows you
5 that each patient is very different and their utilization
6 of resources is very different. If you look at a
7 historical bundle, they have looked for commonalities of
8 care and cost. We see in this population that there's
9 quite a bit of difference between care and cost needed, yet
10 we're proposing only one single payment rate. I think the
11 committee should take a look at the fact that in other
12 payment systems, when there's a large distribution in care
13 and cost items, the bundle has been broken down into
14 separate payments, not one standard payment for a large
15 group.

16 Some other things that need to be considered.
17 This population is highly dual eligible in the Medicare
18 field. About 15 percent of patients are Medicare/Medicaid.
19 There's about 40 percent in this population, which means it
20 comes with that kind of unique home and social
21 characteristics. But in addition, will states pay the
22 20 percent co-insurance on a bundle? Currently today, many

1 states don't pay co-insurance on pharmaceuticals. We're
2 not sure that they're going to pay the full new composite
3 rate difference. What implications are there on this
4 20 percent? Theoretically you'll assume it's going to be
5 funded. Will it in fact be funded? That research needs to
6 be done.

7 Number of prescriptions, for example, in this
8 population is about 6 to 8 oral meds. In the normal
9 population it's probably plus or minus 2. Again, that's an
10 indication that these patients are much more chronically
11 ill and their needs are quite different than a Medicare
12 population.

13 I found the discussion regarding the quality and
14 the lack of relationship to payment just extremely
15 disturbing. We know the one thing that's highly variable
16 in the population from the data is EPO utilization, and we
17 saw that there was a significant correlation to anemia
18 outcome based on utilization. Yet again, this bundle isn't
19 taking that into consideration. I think if you think about
20 quality these types of items have to be considered.

21 The discussion around alignment of incentives
22 with physicians is I think totally appropriate. They drive

1 a lot of the choice between a home modality and an
2 in-center modality. They are the prescriber, as Chris
3 pointed out, of the medications. They are not currently
4 aligned necessarily with a bundle. If that compresses
5 reimbursement to a facility, that will not drive, and
6 shouldn't probably drive, a change in their prescription
7 patterns, but yet will put the population at risk.

8 Another element that wasn't addressed today is
9 that a very significant cost of our treatment, being EPO,
10 is from a single-source manufacturer. They will by
11 definition change their pricing. How does the bundle
12 address that? How will the bundle stay in touch with what
13 it cost a provider to provide that item? You cannot ignore
14 that. We're the middle man. The doctor's ordering, the
15 manufacturer's making decisions. We by definition have to
16 hit a quality outcome if you choose to put it in there. If
17 you don't, I think as Mike said, we're kind of at a point
18 where most of our patients are hitting the target. We're
19 in a box. If that continues to be a target, you need to
20 address that point.

21 I think in terms of the data analyses here
22 presented, still I have a little bit of concern around the

1 lab data. It wasn't clear to me that that was analyzed
2 well and not sure where that's coming from, and who's
3 ordering it, and how we ultimately drive the right
4 behavior. I'm not against it being in the bundle, but I
5 think more work needs to be done considering how we would
6 actually change the behavior surrounding that. I think
7 that's additionally true about the other items in 1D
8 because they're ordered in a host of settings and how we
9 might get our hands around that to rein that in I think is
10 very challenging as an outpatient provider.

11 Probably the last point I'll talk about is pay-
12 for-performance. I think they are important elements.
13 They should drive proper clinical behavior. But if you're
14 going to have those things in the bundle payment system,
15 you must first decide that the unit of payment is correct.
16 We believe that the current payment is clearly underfunded.
17 That is presented in the MEDPAC work. We don't believe, as
18 Mike pointed out, that there's room to decrease dose in
19 anemia without changing outcome, so those things are very,
20 very important as you move forward. Thank you.

21 CO-CHAIRMAN AUGUSTINE: Thank you, Ann.

22 SPEAKER: We have materials that I'll leave here

1 or you can pass it around, that summarize Leanne's points.

2 CO-CHAIRMAN AUGUSTINE: Thank you.

3 Dolph Chianchiano from the National Kidney
4 Foundation.

5 MR. CHIANCHIANO: Thank you for the opportunity
6 to address the board. In response to this morning's
7 discussion, if all patients in a unit are not required to
8 participate in the bundling demonstration, it is absolutely
9 essential that every patient in a unit be entitled to elect
10 to participate in the demonstration.

11 In regard to this afternoon's discussion and the
12 agenda for the next meeting, I would like to draw your
13 attention to some issues raised in the department's report
14 to Congress, entitled, "Toward a Bundling Outpatient
15 Medicare ESRD Prospective Payment System," as well as
16 features of the RFA for the ESRD Disease Management
17 Demonstration Project.

18 The report to Congress includes this warning:
19 "Efforts to collect and evaluate quality measures will be
20 essential to ensure that clinical outcomes do not decline
21 as facilities respond to the new financial incentives
22 created by a bundled prospective payment system." As Brady

1 mentioned this afternoon, we can't rely on the conditions
2 of coverage to ensure quality assurance. If for no other
3 reason -- it's very unlikely that the final rule will be
4 published before the bundling demonstration begins.

5 As was noted, the bundling demonstration is not a
6 disease management demonstration, however there are
7 parallel considerations in the design of any demonstration
8 project. The RFA for the ESRD disease management demo
9 states that "CMS will monitor patient care to ensure that
10 patients receive at least the same level of medically
11 necessary services and medications, as determined by the
12 patient's physician, as they received prior to enrollment."
13 I think maybe the Advisory Board should consider such a
14 proviso in the bundling demonstration.

15 The bundling demonstration should also be
16 designed to monitor access to modalities, referrals for
17 transplantation, patient satisfaction, and patient quality
18 of life, as is in the case with the ESRD Disease Management
19 Demo Project. Thank you.

20 CO-CHAIRMAN AUGUSTINE: Thank you very much,
21 Dolph.

22 Finally, Jim Lordeman. He's a consultant to RCG.

1 MR. LORDEMAN: My name is Jim Lordeman. I'm an
2 independent consultant, but I used to be employed by the
3 Renal Care Group and now I'm an independent consultant that
4 is representing the Renal Care Group. I wanted to be
5 absolutely certain to have it made a part of the record,
6 given the transaction that was announced a couple of weeks
7 ago. I hope my consulting agreement will be continued.
8 And in fact, every comment made by Dr. Lazarus has been
9 brilliant, absolutely just sheer brilliant.

10 I think first an observation that probably nobody
11 can do anything about, but I thought it might trigger some
12 thoughts. If you look at MMA, Section 623e and f, the
13 language used in those two sections are really strikingly
14 different. 623e, which of course is the auspices of this
15 group, is extremely specific. It says you will do this,
16 there will be a demonstration, it will start on this date,
17 it will include these things. 623f, asks for the report by
18 October 1, it seems to suggest -- describe the feasibility,
19 describe the mechanisms. And, oh, by the way, throw in
20 some other things that the secretary may deem appropriate
21 as he feels fit.

22 That's striking to me because it would be

1 interesting that in coming up with a report that has a
2 little bit more room for creativity, if somehow in the
3 demonstration project we didn't capture the opportunities
4 to embody in the demonstration project some of that
5 creative thinking, that might be able to be built into the
6 report. Again, there's not a lot to do. That probably can
7 be done by this committee. The language is pretty clear as
8 to what this committee has to focus on, and I guess we're
9 pretty much left with that.

10 I have another comment or question to ask the
11 committee to try to think about. I'll phrase it this way
12 just to maybe stimulate the thoughts. It's probably a
13 wacky way of stating it. If somehow the KECC people could
14 build this brilliant model that could calculate the
15 remainder of lifetime costs for a patient as soon as they
16 hit creatinine clearance of, let's say, maybe 30 or 60,
17 some number of serious degradation of kidney function -- if
18 we then knew this patient is going to cost \$417,000 for the
19 rest of their lives -- if we then knew that amount and
20 prepaid that to some team of providers undoubtedly led by a
21 nephrologist, what behaviors do we think we would then see,
22 given that kind of an incentive?

1 Obviously that is totally non-practical. But as
2 you think about what behaviors that might incentivize, I
3 think it would be very clear that a lot of behavior changes
4 would occur in the CKD arena, and I would I guess urge this
5 committee -- again, we're kind of stuck with a bundle
6 project, and it's got to have this and it's got to start
7 here. But at least to the extent that pay-for-performance
8 initiatives can be layered on top of a new bundled
9 mechanism, I think, in terms of where the big impacts can
10 be --

11 I read the transcript of the first meeting. I'm
12 sorry that I missed it, but everyone spoke about kind of
13 broader themes and issues in improving what we do for these
14 patients. I think the big opportunity is likely to result
15 from things other than is it 1A, or 1C or 1D. I think this
16 is a little bit tinkering around the edges when there's
17 bigger issues that can have a bigger impact. But
18 nonetheless, I recognize how difficult this is and the
19 directive that's been given, and appreciate all the work of
20 the committee. Thanks.

21 CO-CHAIRMAN AUGUSTINE: Thank you, Jim. In fact,
22 as you pointed out happily, this group has not been

1 chopped, and there's a lot of serious, thoughtful
2 deliberation here, and it doesn't just pertain to the very
3 concrete bundle recommended in E, but a different
4 prescription is given in F, and then there's a
5 cross-reference as well. So there's a lot of ambiguity
6 which allows a little more latitude to this group to
7 provide a recommendation that we think is in the best
8 interest of the program, the providers and the patients,
9 and meets the IOM's aims on the back wall. So thank you
10 very much for your comments, everyone.

11 Bob, closing remarks you'd like to make or wrap
12 up?

13 CO-CHAIRMAN RUBIN: Although it sometimes didn't
14 feel like it, I think we got a lot accomplished today.
15 It's a lot of data to digest, and I think a good to-do list
16 for the staff in preparation for the upcoming meeting.
17 Clearly the committee members actually read this two inches
18 or so of material that was dispatched to us, and it was not
19 easy reading. So thank you.

20 MS. MAGNO: I have just a closing comment. The
21 next meeting is scheduled for July 14th and 15th. We expect
22 it to be at the BWI Marriott Hotel, which all of you would

1 have passed on your way here today. The details with
2 respect to meeting times will be published in the *Federal*
3 *Register* the end of June. The fourth Friday in June is
4 when we expect to publish the notice in the Federal
5 Register, and that will have the exact times that the
6 meeting will start and end, both days. Thank you.

7 CO-CHAIRMAN AUGUSTINE: I don't have any profound
8 words. I just want to thank everyone for letting us have a
9 little bit of your time today. As always, anytime we get
10 this community together it's an enlightening discussion.
11 And I am more proud of the community that I am from. Thank
12 you very much. We'll see you at the next meeting. We are
13 adjourned.

14 (Whereupon, at 4:42 p.m., the meeting was
15 adjourned.)
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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.

Lisa L. Dennis, CVR