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ADVISORY BOARD ON THE DEMONSTRATION OF A BUNDLED CASE-MIX ADJUSTED PAYMENT SYSTEM FOR END STAGE RENAL DISEASE SERVICES

FIRST MEETING

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The above-mentioned meeting was held on Wednesday, February 16, 2005, commencing at 9 a.m., at the Hyatt Regency, 300 Light Street, Baltimore, Maryland, 21202, Second Floor, Baltimore, Maryland 21202 before Robert A. Shocket, a Notary Public.

ADVISORY BOARD PARTICIPANTS:
BRADY AUGUSTINE (Co-Chair)
ROBERT RUBIN, M.D. (Co-Chair)
JOHN BURKART, M.D.
THOMAS CANTOR
PAULA CUELLAR
PAUL EGGERS, Ph.D
BONNIE GREENSPAN, RN
J. MICHAEL LAZARUS, M.D.
WILLIAM OWEN, M.D.
NANCY RAY
KRIS ROBINSON
JAY WISH, M.D.

PRESENTERS:
RICHARD HIRTH, Ph.D
MARC TURENNE, Ph.D.
JACK WHEELER, Ph.D.
ROBERT WOLFE, Ph.D

ADDITIONAL SPEAKERS:
CHRISTINE BARNETT
RICHARD CRONIN, M.D. (Public)
LINDA MAGNO
BRIAN PEREIRA, M.D. (Public)
LANA PRICE
TERESA RUDISILL

ALSO PRESENT: HEATHER GRIMSLEY, PAM KELLY, HENRY BACHOFER

REPORTED BY: Robert A. Shocket

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

MS. MAGNO: Good morning and welcome to the first meeting of the Advisory Board on the Demonstration of Bundled Case-Mix Adjusted Payments for ESRD Services. I'm Linda Magno. I'm the Director of

the Medicare Demonstration Program Group at the Office of Research, Development and Information, and I'm the CMS Executive Officer for this committee. We appreciate the members agreeing to serve on the Advisory Board and welcome the public to this meeting.

As you know, the Advisory Board was mandated by Section 623(e) of the Medicare Modernization Act. We believe the Advisory Board will provide significant input into the development of an important demonstration for the ESRD community.

We appreciate the board members' corporation with the process of being appointed to this committee and with its links. We recognized that there were tight timeframes but wanted to hold our first meeting as soon as possible after the Secretary approved board memberships in order to begin the

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development of this demonstration design.

As we get started, I would like first to take time to quickly introduce the advisory committee board members and CMS staff. And, you'll hear from each board member later this morning. I would like also so that people can identify, want to know the people from the public, to have each board member stand as I introduce you. One of our co-chairs is Dr. Robert Rubin, clinical professor of medicine at Georgetown University School of Medicine. Good morning.

DR. RUBIN: Thank you.

MS. MAGNO: Our second co-chair is Brady Augustine, with the Centers for Medicare and Medicaid Services. We also have Dr. John Burkart, Professor of Internal Medicine and Nephrology at Wake Forest University; Thomas Cantor, Biochemist, President and Owner of Scantibotics Laboratory; Paula Cuellar, Nurse, R.N., Dialysis Center Director at the University of Chicago Hospitals; Dr. Paul Eggers, Program Director for Kidney and Urology, Epidemiology, at the National Institutes of -- I'm sorry, NIDDKD, the National

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Institutes.

DR. EGGERS: It rolls right off the tongue, doesn't it?

MS. MAGNO: It certainly does, particularly, you know, it hits you with a lot of Ds all at once. Bonnie Greenspan, registered nurse, and a health care consultant, J. Michael Lazarus, M.D., chief

medical officer and senior vice president for clinical quality at Fresenius Medical Care; Dr. William Owen Junior, adjunct professor of medicine at Duke University School of Medicine and senior scholar at the Fuqua School of Business; Nancy Ray, research director with the Medicare Payment Advisory Commission; Kris Robinson, Executive Director of the American Association of Kidney Patients, and Dr. Jay Wish, President of ESRD Networks 9 and 10. Thank you, all of you.

I would also like to introduce CMS contractors and contractor staff. In the interest of moving things along, I'm going to ask all of the CMS Office of Research Development and Information staff to

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stand. Their names are in the handouts and on the screen so if all of the ORDI staff could stand. And they're all wearing name tags and will all be happy to introduce each other.

And then the CMS Center for Medicare Management staff, if I could ask you to stand. Thank you. And then we have our contractor staff, who will be speaking later today. And I'm going to ask them to stand. Robert Wolf, Richard Hirth, Mark Turenne and Jack Wheeler with the University of Michigan and they'll be doing some presentations later today.

Now, as we move on, I wanted to talk a little bit about what FACA is, the Federal Advisory Committee Act under which this committee will be operating. The Advisory Committee Act became law in 1972, and it established assistance to govern creation and opportunity of advisory committees in the executive branch of the federal government. The Federal Advisory Committee Act governs any group that a federal agency convenes to develop formal findings or proposed recommendations, where one or more of the members of

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the group are not federal employees. So it applies to any federal agency of which we are one.

The role of the advisory committees is to draw upon the expertise and experience of the membership. The committee is utilized to advise or make recommendations on matters relating to programs, responsibilities, activities of the department or agency and as part of the Advisory Committee Act the public is afforded an opportunity to actively take part

and participate and observe the decision-making process.

The requirements for the Federal Advisory Committee are that we file a charter, keep detailed minutes, that the committee be chaired or attended by a federal official, that we provide advance notice of public meetings -- those meetings are open to public participation as well -- that we make our minutes, reports and records available to the public, and that we, the committee be constructed in a way that is fairly balanced in terms of points of view. And these committees are limited to two years unless specifically

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exempt.

And I would like to point out that this particular Advisory Board was chartered through 2008 to cover the three-year demonstration period that is mandated by MMA to begin next January, 2006. Also, the minutes of the Advisory Board meeting will be posted on our Web site and the transcript will be available upon request.

At this time, I would like to introduce Chris Barnett from CMS Ethics Office and after she has addressed ethics questions and other questions you may have, then Teresa Rudisill from the CMS Human Resources team will swear in board members. Chris?

MS. BARNETT: Good morning. First I would like to say that the members of this committee have received an ethics training video. I did bring some additional materials but I did want to clarify the roles of the members of this committee. We have three different types of members of the committee. Some of the members are government employees and those members are Brady Augustine, Nancy Ray and Paul Eggers.

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In addition, we have some employees who we refer to as special government employees and they have been asked to serve on the committee because of their expertise. Those members are Robert Rubin; Thomas Cantor; Jay Wish; Bonnie Greenspan and Bill Owen. These special government employees are subject to the standards of conduct and the conflict of interest laws. We have done a conflict of interest analysis on these people. And I have, these materials are for you.

In addition, we have representative members. The representative members have been asked to

serve because they are here to represent the industry that they are from. They are not government employees and they are not subject to the standards of conduct or the conflict of interest laws.

I have one form and I'm not certain where everybody is sitting. I think you're spread out a little bit. So, if I mentioned your name and described you as an SGE, please take these as I pass them around. A foreign activities questionnaire -- from this way and from this way -- that needs to be completed and

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returned. I have a summary of the conflict of interest laws as they apply to SGE, particularly advisory committee members.

Although these laws apply to them, in some cases they don't apply to the same extent that they would for regular government employees. And I have a few extra ones that I will leave here today if anyone is interested. Actually, I have a lot of those. Okay. SGEs are also subject to Hatch Act restrictions but only during the time you are serving on the committee. In addition -- how many people do we have on this side?

DR. WISH: Two.

MS. BARNETT: Two, okay. I have a copy of the governmentwide standards of conduct. These are the topics that were mentioned in the video that you saw, and also a copy of the Department's supplemental standards of conduct. Does anyone have any questions? Yes?

MR. CANTOR: A couple more.

MS. BARNETT: It's important to keep in mind that as an SGE you are here in the government's

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behalf, and that the interest that you will be serving on this committee will be that of the government. I also would like to remind you that there are certain recusal obligations that you may need to be aware of. If any matter comes before the committee that would directly affect a financial interest of anyone who is serving as an SGE or regular employee, you cannot work on that matter without seeking ethics advice so you will be obligated to recuse yourself from participating at that time. There are no questions? Any questions from you? Okay.

It turns out we're going to have to delay the actual swearing in because Teresa Rudisill is not

yet here. I suspect she may be stuck in the same traffic that delayed some of the rest of us. So, with that I'm going to turn the microphone over to our co-chairs, and I think we'll go ahead and start an overview today and we'll just have to start to do the swearing in just as soon as Ms. Rudisill gets here.

MR. AUGUSTINE: Thank you, Linda. All right. Now we are calling in the rest of the

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University of Michigan Kidney Epidemiology Cost Center staff so bear with us for a second. In fact, they don't need to hear our opening spiel so let me go ahead and start if I can concentrate with the noise in the background.

I feel kind of like I'm at a family reunion. As many of you know, I had the privilege of being a senior executive for ESRD and CMS for two years. I moved into a new role in the agency about four or five months ago. You know, kind of as they said in The Godfather, you know, every time I leave, they call me right back.

But, truly it's a labor of love and I'm truly honored to be here. I want to thank all of you for participating because I know all of you have other things to do like take care of patients, provide counsel and advice and actually run the office's facilities. So, I know that what you are giving up is quite valuable and I hope that as we work together we will be able to make the best value of this time so it will be worth your while.

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So with that said, I also want to thank my co-chair, my eminent co-chair, Dr. Rubin. It's a pleasure to serve with you. Dr. Rubin not only has a breadth of knowledge with regard to the kidney community and a well-respected leader in the field but Bob also has provided excellent service to the federal government through not only as a consultant to CMS on various activities but also as an assistant secretary. So, when I saw that Bob had kind of signed up for this, it made me feel a lot better about what we were going to be able to accomplish. So, Bob thank you.

As we all know, I'll make a few, this will be my summary statements. I will talk about a minute or two and I won't talk later on when we do the member perspectives. We all know the ESRD program and

Medicare at large are changing. You know, our job, at least CMS's job is to ensure that that change is a responsible change. And responsible change requires that we listen and learn from the community from those who actually provide care. We really want to ensure that that care does not come, that the care and

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efficiency doesn't come at the cost of access.

And speaking of quality, one thing I do want to do this morning, I want to spend a second even though it's a little bit off topic to recognize those in CMS who work so hard and diligently on the conditions for coverage proposed rule and if you could maybe stand for the group real quick, Teresa Casey's not here I don't think yet.

MS. GRIMSLEY: She's over here.

MR. AUGUSTINE: Teresa Casey, she was the lead writer and did excellent work on the conditions of coverage. As well we've got Judy Carey here, in the Serving Subgroup that did excellent group as well, and then Lana Price, and her payment division did excellent work as well. And, so, many of the kudos and congratulations. I know that it may not be perfect when we look forward to comments but I will single those three out and their teams for doing very excellent work not only getting it done but doing it as best we could.

So, one of the things I do want to mention

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today is being someone who has a lot of friends in the community, I have heard a lot of comments about, there's a lot of comments about maybe feeling that this boat is moving too fast without enough input from the community. And I do want to recognize a wonderful article that Brenda Dyson wrote, President of AAKP in October or November of last year.

And basically what the article stated was that us as a community need to take a leadership position because the world is changing and it's best that we lead the way as opposed to being led. I think that's an adequate summary, correct? And that we really should put patient centers and quality at the forefront. So that said, you know, one of my favorite quotes is Henry Kenneth Galbraith who said that "Leadership is primarily about tackling the major issues of the day. That and not much else is

leadership."
So, that's why I'm excited that this group, this community can come together with this panel and provide leadership and direction to the Secretary and

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to CMS so that we can devise a payment system that to the best of our ability works. No payment system is perfect but we'll work to address the major issues that exist today, thanks to a lot of work like from Nancy Ray at MEDPAC, and many other advisory bodies. We've got a lot of good data and analysis to work with. So now we just need to bring the expertise of the community together to try to make some recommendations.

So with that said, that's about as much as you're going to hear me speak over the course of the day. We'll get to the first slide, which is the agenda slide. We have a lot of ground. We have a very ambitious agenda today. This morning we will review a charter and the charter of the committee, get the members' perspectives on bundled payment, review the history and current status and prospects for the composite rate system, discuss possible goals for a new system, and take a fast tour of some basic data to kind of tease us and get us thinking about what we're dealing with.

This afternoon we'll get more into the

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nitty-gritty and my colleague and co-chair will be leading most of the discussions in the afternoon. The three major issues that we must grapple with as we move forward, what's the scope of payment, i.e., what should the bundle payment include, what components of care of the dialysis units are actually accountable and responsible for, and we'll also have a short introductory discussion of case-mix -- oh, that was the third one. Excuse me. We'll also have a short introductory discussion on the fourth major issue which is case-mix.

We'll conclude today's business with an opportunity for public comment and a summary of our next steps and where our future meetings will be. Could we go to our next slide, please? So here are our objectives. Above all what we want to do is listen and learn from you, members of the committee, concerning bundled payment dialysis services.

We hope for us today from our discussions

we can build a consensus on the general goals for a bundled payment demonstration project. We also want to develop a common understanding of the limitations and usefulness of existing data from activities we may need to undertake to gather additional data to help make our payment system as good as it can be.

We hope to identify to the extent possible the general duration on the key issues in the design of a bundled payment system so that we can focus the analysis that is at our disposal to provide us as much value as we possibly can. And finally we want to identify the basic questions that this committee's members believe need to be addressed for us to go forward. The next slide, please. Now for the --

MR. BACHOFER: Just do the administrative.

MR. AUGUSTINE: Yeah, for the administrative issues, we are going to have a lunch break at about noon. The restrooms are if you go out the door, most everyone here has been in this building before but you go out the door and it's kind of dangling to the left. That's an appropriate description.

Additionally, for committee members we have distributed an evaluation form so if there are ways we can improve, since we are encroaching upon your time, if there are ways that we can improve the activities of this board, committee, feel free to fill that out and you can give it to myself or Dr. Rubin or the executive officer, Linda Magno, and we'll make sure that if there are concerns that need to be addressed, we will take care of them to the best we can.

And one note for the public. There will be an opportunity for comment this afternoon. We please ask you to refrain from comments, discussions during the course of our deliberation. Additionally, there will be during the lunchtime this afternoon, the lunch is for board members and so we will be meeting, that will be a separate lunch.

Not to exclude the public or anything but it's just a special lunch that we provide for committee members. There are plenty of opportunities for people in the audience, in fact, we have actually a really good location for people to eat across the way, at the Inner Harbor and whatnot. So, if at any time anyone

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would like to share opinions or data with us, you can submit the information to Linda Magno and her information is in the packet, or, you can send it, we have an e-mail address as well. And it's, what is it, ESRD --

MS. GRIMSLEY: Advisory Board.

MR. AUGUSTINE: "esrdadvisoryboard" -- that's all one word -- "@cmsdothhsdotgov." As well we have a Web page where all the documents, for example, Federal Register notices, agendas and whatnot are posted. And you can get to that at "wwwdotcmsdothhsdotgov/faca/esrd." Go to the next slide, please.

So now we -- go to the next slide. We've already done that. So, we're going to take a step back now and kind of look at what our charge and charter is. Next slide. So Section 623 of MMA addressed ESRD-related topics, something that's kind of, all of us are quite familiar with. As Linda pointed out earlier, Section 623(e) is the specific section for the Medicare Modernization Act that includes expanded

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bundled demonstration project, and describes the activities of this board. Section 623(f) of the MMA includes discussion on the report to Congress that is due October 1st of this year, on an expanded bundle.

Now, one of the things that we've noticed is there are different language in the two sections, 623(e) and 623(f), regarding what should be included in the expanded bundle. Our research and demonstrations group has interpreted this as requiring at a minimum that the expanded bundle be tested in a demonstration include drugs, biologicals and related laboratory tests.

Among other implementation issues we are asking for input from this Advisory Board on the scope of services to be included and the expanded bundle in the demonstration. Next slide.

So, these are the major topics that we're going to be discussing and seeking your input on, what are we going to include in the bundle, how to adjust payment to reflect patient needs by either case-mix, how to implement a requirement that all services

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included in the bundle are billed to and through the

dialysis facility, the role of disease management in the demonstration, and pay-for-performance concepts and finally what are the selection criteria. Our first and second meetings will focus almost exclusively on the first four of these topics, being the scope, case-mix, payment, consolidated billing of payment and the pay-for-performance.

One of the things that MMA sets up is we can't have any more than four meetings a year so this is kind of our schedule. We are ambitious this year with four meetings and then once the demo begins early next year, we're still going to have some, provide counsel and oversight to the ongoing operations of the demo. We'll have two meetings next year, one in 2007 and one in 2008. Next slide.

MS. MAGNO: I would like to take you through the projected timeline now. It's very aggressive for 2005, as Brady said, but really one that was imposed on us by Congress. So we are working towards the statutory implementation date for the

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demonstration of January 2006. With that in mind, we expect that we will need to publish a solicitation for organizations interested in participating in the demonstration this coming July.

To make sure that the Advisory Board has input into the design of the payment system to be demonstrated, we are planning three meetings of the board, today's and two additional meetings before the end of June, when solicitation must begin to work its way through the clearance process in CMS and the Department of Health and Human Services.

And then we plan a fourth meeting in the fall to review the status of the solicitation and to revisit any issues that may have surfaced through the clearance process in the development of responses to solicitation. We'll address the meeting schedule again when we wrap up this afternoon. Thank you.

MR. AUGUSTINE: Teresa is here, okay. We're going to do the swearing in ceremony presently now that we have our HR representative here.

MS. RUDISILL: Good morning, everyone. I

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am Teresa Rudisill and I am from the Baltimore Human Resources Center. I'm going to swear a couple of people in so when I call your name please stand, raise

your right hand, and repeat after me. Thomas Cantor, Bonnie Greenspan, Robert Rubin, Jay Wish and William Owen. Okay.

"I -- state your name -- do solemnly swear that I will support and defend the Constitution of the United States against all enemies, foreign and domestic, that I will bear true faith and allegiance to the same, that I take this obligation freely, without any mental reservation or purpose of evasion, and that I will well and faithfully discharge the duties of the office on which I am about to enter, so help me God."

(Members sworn)

MS. RUDISILL: Congratulations. Okay. Did everyone sign their form?

MR. AUGUSTINE: Let me just add quickly that we are, this is one board. Even though it looks like some people are treated differently, some of the members have different characteristics than others but

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all of our purpose is the same, to create an expanded bundle that, as best we can that meets our goals.

All right. So, I have been boring enough this morning. Now I can be a little more open. So, I feel like I'm back in college where the professor reads directly from the book and everyone gets bored and falls asleep. So, that's why I'm excited we're at the part of the meeting where the board members can kind of discuss their experiences with an expanded bundle and where they think the pitfalls are and where we need to be going.

So, each of you has been asked to prepare a five-minute statement briefly summarizing your professional background or offering some perspective on why you are here and why this is important to you, and outlining your perspective on the issue of bundle payment. As we go around the table, we'll keep an eye on time because, as we know, we're really tight on time today. We have an ambitious agenda.

So, if it gets, we actually have seven minutes available. That's why we you had write it for

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five and if we get at six, I will make a little gesture to let you know that we are in the closing session of your piece. We don't mean any disrespect by the cutting people off. I know that everyone at this table cares passionately about what we're talking about and

probably could talk forever but then we wouldn't get as much of the work done this afternoon as we would like to.

So, we will be capturing key issues that are raised. We're going to go have a parking lot here so if there are things we need to come back to or address that come from your discussions, we're going to write them down to make sure that we close the loop, since all the board members have all their, have all these items satisfied to you. So, we can start. I think a good beginning would be, we'll start with Kris Robinson. If you could go ahead and give us --

MS. ROBINSON: Sure.

MR. AUGUSTINE: Oh, I'm sorry. Dr. Bob Rubin, let's let Dr. Bob Rubin go first. He's the co-chair and then we'll move to Kris. I'm sorry.

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DR. RUBIN: I thought we wrote the script down so you could --

MR. AUGUSTINE: I'm sorry.

DR. RUBIN: That's okay. I also thought you were going to get the budget provided for the green light, yellow light, red light.

MR. AUGUSTINE: That would have been nice.

DR. RUBIN: In any event, thank you very much. It's a pleasure to, I think, to be here. Let me quickly state a little bit about my background and then some thoughts about prospective payment in general and this in particular and perhaps amend a little bit the comments that my co-chair made, at least from the perspective that I think this committee was actually charged with and, more importantly, what we were not charged with.

So, as you heard, I'm a nephrologist, currently at Georgetown. I was also a consultant. And, for purposes of this committee, in, from 1981 to 1984, I was assistant secretary for planning and evaluation at HHS and in that capacity was chair of the

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intra and interdepartmental groups that were involved in constructing the second prospective payment system for the department, the first being the composite rate for ESRD. And the second was the inpatient hospital prospective payment system.

And some of the principles that were used there I think might be constructive to think about here

as we go forward in the deliberations. The first is, we wanted to reward efficient providers and disincent inefficient providers. Second, to do this is that all providers had to feel that the playing field was level. To do that, there were a bunch of techniques that we used, some of which were successful and some of which were not successful and have since been modified.

But, most importantly, in looking across the country at impact analyses, this prospective payment system and indeed any prospective payment system really requires a random distribution of patients as to severity of illness as well as to underlying diagnoses. And, it was for those reasons, for example, that in the original inpatient prospective

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payment system, cancer hospitals were exempt and teaching hospitals got what was a, what turned out to be a very generous addition under the concept that perhaps they had more severe cases than other hospitals.

And, at some off-time we can debate whether those were correct or incorrect but the point was that we at least made those choices volitionally. They were not unintended consequences. So, moving from the broad generalities to the particular about this bundled payment demonstration, I think that clearly what everybody would hope to see is that the demonstration shows that you can have a bundle, that it's constructed correctly and that for patients it means at least equal to if not higher quality of care than what they're currently receiving.

And for providers and facilities, it means that they don't go broke trying to do it as at least one of the two participants in a previous demonstration would have, had this particular methodology or requirement gone forward indefinitely. I should also

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say that as a consultant I was involved in the evaluation of the managed care demonstration that CMS had previously.

So, clearly if we're going to have a, recommend a bundle for a demonstration -- and here's the subtle amendment I would like to make to what Brady Augustine said -- is what we're constructing here is an experiment. We're not constructing something that hopefully will go forward in legislation before we have

had a chance to have the experiment because otherwise why bother with the experiment.

So, what we're trying to do is do something that, to fall back on a principle that we all, the physicians in the group learned is first we want to do no harm, do no harm to the patients and do no harm to the facilities, the providers and also the government. Because, depending on how this is constructed, the government could actually wind up spending more than that what they might have under the current system.

Secondly, the features that a bundled payment system should have is predictability, equity

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and an incentive for quality. In order that we need to have the best data we can and we need to have it not only on a systemwide basis, on a facilitywide basis but also to a very large degree on a patient-specific basis. And, I think that if we don't have those, we need to do things that err on the side of generosity so that we can achieve the goals of equity, we can achieve the goals of incentive for quality and we can have safeguards so that patients don't do any worse than they do currently.

So, those are really the things that I'm going to be looking at as we go forward through these meetings and look at the data and see how we can recommend what can be reasonably included in a bundle and what we simply don't have the data for, not through the fault of anybody but perhaps suggest ways that CMS can collect that information in the future, either through targeted research or expanding the level of data and the kinds of data that they collect. Now we can have Kris go.

MR. AUGUSTINE: Thanks, Bob.

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MS. ROBINSON: I'm Kris Robinson. I'm the Executive Director of the American Association of Kidney Patients, I myself a patient of almost 19 years with a living-related kidney transplant. What do we hope the payment based on expanded bundle accomplishes, achieves? Well, I can only speak from the patient perspective. And I want to begin by stating the statistical fact and that's that patients starting today on ESRD have a life expectancy of less than five years.

And, you know, patients with colorectal

cancer or patients with AIDS have a higher life expectancy. So, A, it could be into patients, we know that patients can live long lives, good quality lives and that my hope would be that any innovation, whether it's restructuring of payment or clinical outcomes would take into thought and to evaluation on how it can increase life expectancy for patients to. So I have two hopes in that regard.

First my hope is that the demonstration of project will provide for the first time critical-needed

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data about the clinical value of an expanded bundle of services. Congress and CMS has been interested in this for many years, since 2000, and we haven't seen much independent analysis on an expanded bundle, even among our fellow CMS stakeholders. When we talk about bundles, you know, there's so many ways to look at it. Composite rate is certainly a semi-bundle going all the way to managed care, which is a full bundle, so for us to discuss on what we mean by bundling.

And second in terms of the demo project, the best case is that the new bundle payment options give dialysis facilities more flexibility to provide personalized care for patients because we know that personalized care can also mean a longer life expectancy and less disability. What are the risks? As patients we want to ensure that all patients have access to all needed care and that the expanded bundle will actually not provide financial incentives for providers for less care.

As Dr. Rubin stated, measurement is the key to everything here. It must be able to be measured in

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order for something then sure to be done. And, I think that quality is a huge issue. I'll note that AAKP has had a long-standing commitment in the pay-for-performance department. In fact, sometimes to the chagrin of our colleagues in the kidney community, we have always stated that reimbursement should be tied to quality measures and outcome. And we feel strongly that how payments should be crafted as a reward or a withhold is a tougher issue and we've got a lot of hard work in front of us as we discuss the bundling effort.

We always want to keep in mind, too, that the smaller, independent facilities, that's a tough question. How do we make sure there are enough

resources going to the smaller independent facilities? And then we have the question of what's going to be included in the bundle. We believe at AAKP that there's substantial literature and documentation showing that clinical care can benefit but we don't necessarily get that information out there. We have a great new breakthrough initiative with Fistula First by CMS. It's great work. It's work that started being

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shown over 11 years ago.

So, we want to ensure in the bundling program that we do, that we use information that is out there and can advance in the future as we work with the bundling demonstration project, include new clincial performance guidelines and measures. So, I'm looking forward to participating with all of you on this committee.

MR. AUGUSTINE: Thanks, Kris. Tom?

MR. CANTOR: I'm a biochemist. I come from the background of laboratory science as well as business. And, in 1973 I set out as a life goal for myself to take the knowledge of biochemistry and to translate it into patient benefits. I have contributed to science by publishing articles and some books and patents. And my team, I started this company in 1973 in my garage with just myself and $130. Today it's a team of 400 people.

The team has been directed, I was very concerned in the eighties when we identified the patient in Massachusetts who had been misdiagnosed

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through a false positive of a pregnancy, HCG, type of test as having trophoblastic cancer and had received chemotherapy in error. And as a result of that we developed a chemical called the false positive blocking agent that is currently used for about 50 million cancer tests per year worldwide and helps to prevent these unnecessary surgeries and chemotherapies.

In the other area of laboratory science, we have developed laboratory controls which we have worked together with in the countries of the U.S. and France and Germany, U.S., Finland and Italy. And what these have done, have been to protect patients from mistreatments by indicating when a test is losing its accuracy through a shift. In 1998, we discovered a new parathyroid hormone, which is a kind of regulatory

hormone to parathyroid hormone and turns out to be important for more appropriately guiding Vitamin D therapy and preventing unnecessary parathyroidectomies.

My concern with the bundle is in the area for both Medicare Trust Fund, that the money which is, which is, of course, as the term trust is used

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appropriately, and also for patients, I would like to see a measure whereby patients can be tapped into by way of a satisfaction form. We also manufacture a pregnancy test kit called First Response and Answer, which is distributed to about a million and a half clients per month here in the U.S. And one of the mechanisms we have been able to tie into the clients with that is to set up through J.C. Penney's a 1-800 number whereby clients can call in. And we get a report of about 300 every month which has been invaluable for us. I would like to investigate whether this could be possible within the renal community.

My concern also is when we talk about outcomes is that many of those outcomes are laboratory values and with the knowledge that we, that I have in laboratory science I know very well how there is a great diversity in lab values depending on the test which is used, the specimen collected, the time of the specimen and so forth.

So, I will be particularly concerned and focusing on the measures of quality improvement as they

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relate to laboratory values, of course the ultimate outcome being mortality and morbidity, but moving beyond that to laboratory values will be an area that I will be particularly concerned with. So, I'm glad to be on this committee and to bring to it the laboratory side as well as a business aspect. Thank you

MR. AUGUSTINE: Dr. Burkart?

DR. BURKART: I'm John Burkart. I'm the nephrologist at the Wake Forest University Medical Center. As far as my background, I'm an academic nephrologist. We have a very busy clinical practice. I have been doing this since 1984, various aspects of nephrology. My academic research interests are the clinical aspects of peritoneal dialysis and frequent chemodialysis and renal osteodystrophy. I also serve as a medical director for the Wake Forest outpatient dialysis units and hence I guess I'm a provider. I'm

here, though, because I want to be involved and I want to improve patient outcome and these comments, by the way, even though I'm a provider, are mine.

We were asked to answer a few questions and

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so I will try to go in order for what we were asked, the first being, what do I hope the bundle payment demonstration project will accomplish, first of all, from the patient's perspective. I mean, after all this is about the patient's -- and you can you fill in the blank for the next word if you want. But I think that the patients also probably feel that it's important that any, any effort the dialysis units spend on gaming the system, for financial gains, would actually be directed towards an indicator that improves patient outcome, not just a measurement on a piece of paper.

I think from a patient's perspective it would be important that this demonstration project would remove any impediments for modality choice. I think it would also be important that it allows patients who perhaps now currently are not able to get a medicine because of certain restrictions, insurance, et cetera, that they can get the medicines that they need to improve their outcomes and that ultimately we focus on improving patient outcomes.

From a facility's point of view, I think

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that we need to be careful that these adjustments do not inadvertently decrease the reimbursement towards facilities. If you are in a large chain, you might be able to make up the losses at one unit from gains in another unit but if you're an independent unit, and a small unit and it just so happens to be that your overall payment is less, it may affect quality of care. You know, I think it's important that we look at things to do that. We need to allow the units to focus their energy on things that improve patient care, not that improves some artificial markers that we send in that influence our financial gain.

What about from the doctor's perspective or a medical director's perspective? Well, I think that it is important that the system allow doctors and medical directors to do, make changes and effect changes in the treatments that affect patient outcome. Now, often this is going to be revenue-generated so it's important that we align the incentives and the

bundling so that improvements in energy actually has an improvement in a patient's outcome. We need to remove

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some of the artificial restrictions on use of or doses of certain medications.

And I hope that the bundle system will allow for patient choice, allow for home therapies, allow for some of the new developments that individual patients may need even though it may be more costly, whether it be home or in-center and allow for technology development.

The second question we were asked is what is the downside risk of expanding the bundle system. And ultimately if things are based on economics, it may force some end-of-life decision for patients based on economics, not medical issues. And I would hope that we don't set up a system that does that. We have to be careful about cherrypicking patients and establishing boutique units which can look at the modifiers in a way that, you know, optimize income.

And, again, small units may be disadvantaged by modifiers. I can tell you that if you just looked at a system of units, some units may end up getting paid less per treatment, considerably less than

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what they currently have been, and others considerably more. If you are in one of those units where it's less, how can you improve patient outcome if you are going to get significantly less money? Therefore, in order to do this, the other question we have is, what three key features should the bundle system have? And the number one thing is, is that we need data. We need real, accurate, standardized data that these pilot, that we can use for a pilot study so that we can then effect a positive change. And as has been mentioned, it needs to be based on data.

I think the second feature is that the adjustment and modifier should be based on standardized indicators that are actually related to the patient-centered outcomes. So we want to pick some indicators that if we do better in that area, the patients do better. Remember, that's the number one thing, the patient needs to do better. One of the things we might want to consider is using a realistic cost. In cost reports that we fill out, they are artificially restricted perhaps in that if we're going

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to determine a baseline, it may be helpful to have a more realistic view of the costs for determining this baseline. So those are the three key features.

What three key features should be avoided in a bundled system? Well, I think we need to be careful about how we do that composite rate adjustment. You know, we're working with, and a lot of patients dialyze at centers that are in there because they're a business. And, so, the bottom line is whatever system we put in place, it's going to be gamed. That's human nature and that's part of business.

And, so we have to be careful and be sure that the things that are there for potential gaming are actually things that will benefit the patient. So, if we work hard to game the system, it's in a way that patients will benefit. We shouldn't have units get significantly less payment. They're already possibly in some units that have minimal reimbursement. This thing should not result in less use or restriction of medications nor we shouldn't transfer the cost of medications to the patient and take the money for the

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dialysis unit, for instance, if there are ways to pay for oral medications and the composite rate includes some medicines. We need to be careful about things like that in a bundle system.

The last question we have is, how can or should pay-for-performance be incorporated into the bundle payment system? And I think this is a little bit more difficult. On one hand you can say bundled reimbursement and pay-for-performance are two different things but I think if you think about it they actually can have the same focus.

And if we focus on the patient, the patient is the focus, and think about getting accurate, standardized data that results in patient-centered improvement and outcomes, this can be a win-win situation. The improvement, there needs to be a team approach. We have dietitians and social workers and nurses and medical directors for a reason and I think if their interaction is a real purposeful interaction, not a put-something-on-paper interaction, we will get improvement.

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I think we need to be careful about what we

compare facilities for. It's not so important how we are doing nationally or networkwise as far as how the individual patients is doing and what our individual historic data looks like and we need to be driven to improve the outcomes at our unit. And, if we really do that, ICQI processes can be real and focused.

We need to be careful about not incentivizing units that are already below the 50th percentile because those units who are performing at the 50th percentile or less end up getting less in their pay-for-performance than they currently are. How can they improve outcome? But we need to be able to have a little bit of leeway in the cost structure so that we can actually develop technology and do something extra for a patient even though we're not getting paid for it.

So we need to standardize the way we collect things. The performance incentive should be related to indicators that improve patient outcome. We need to consider looking at multiple things in a

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patient so that, you know, the patients are achieving all the outcomes, not just that our mean is where it needs to be. This may take an act of Congress because A and B are different but I think it's important that we look at those kind of changes.

MR. AUGUSTINE: Thank you, Dr. Burkart. Dr. Owen?

DR. OWEN: Good morning, everyone. Quite candidly, I'm not certain why I'm here. I'm a nephrologist of average intelligence, which means that probably half the people around the table know more than I do. I have had a plethora of jobs in my career. I've been an academician. I've been a practicing nephrologist. I've been in large enterprise, past president of our professional society, and, lastly, care and love for a couple of family members with end stage renal disease.

Probably in the way of background the area that I am most proud of, however, is with a member of this panel, established an inner-city dialysis unit where, as I like to describe it, homicide contributed

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to us having an adverse standardized mortality rate.

Around the issues that we are addressing here today, I have really three, what I described

contextual points or contextual queries that very much influence my thoughts toward the six questions that were posed to us as panelists. The first of those that I am a little unclear on, quite honestly, is are we talking about end stage renal disease care only or are we talking about medical care of an end stage renal disease patient, and the two are really quite different.

Secondly, I am not too clear, quite honestly, about who the end stage renal disease provider is. I see provider in a lot of slides here thrown around. I'm not sure who the heck the provider is. Is the provider the M.D., is the provider the allied health professional, is it the facility, is it the outside M.D., is it all the above?

And then lastly, I am not confident about what the site of end stage renal disease service that we're talking about is, is it the dialysis unit or is

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it that extended, integrated -- and I put integrated in quotes -- health care delivery system that these folks are taking advantage of.

In terms of the first query that was posed to us, goals of an expanded bundle, I see this as, quite honestly, one of many alternative strategies to drive what I listed out here for myself as seven things, first of all, better service coordination between providers and also for an individual provider. For those of you who care for patients, I'm sure you appreciate that you can improve the way you coordinate what you do since you barely remember what you did the last month preparing for a patient.

Secondly, I see this as a strategy to drive greater attention to value of service. And I am describing value in this circumstance as the ratio of the clinical outcome, and outcome gets a lot of different definitions, to the cost of those services provided.

Thirdly, I see this as a strategy to serve, discharging or diminishing or mitigating the

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distraction that is offered around clerical tasks, and I'm talking about clerical tasks ranging from compliance training to good old-fashioned documentation that doesn't serve the care of the patient but serves the need that someone else has based on distrust of

what I'm doing.

Fourthly, a way of offering greater autonomy in terms of the ability to care for patients. Fifthly, fewer expenses for overhead and that's both in variable as well as fixed costs. Sixthly, a way of rewarding value for the aggregate of stakeholders in the care of patients. And then lastly, as a potential strategy to drive greater scientific and therapeutic innovation, an end stage renal disease program, which I will tell you putting on an enterprise hat and having seen innovation in ESRD providers versus other areas, we are way behind.

Potential risk, as my colleague to my right described it, boutique units, I describe them as concierge dialysis or concierge units. We need to avoid that. And unfortunately there is an opportunity

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for this to result in uneven service quality, limited innovation, reverse patient selection and therefore, of course, limited access to interventions. Key features for the right system, I'm a simplist. I'll describe it with the three features as the right amount of money to the right person at the right time. Things to avoid, all the above, and then lastly as for pay-for-performance, great opportunity for us to do the experiment, what was described by my colleague to my left as a beta test in my mind is an alpha test for pay-for-performance. So, thanks for allowing me to be here.

MR. AUGUSTINE: Thanks, Bill. Dr. Wish?

DR. WISH: Good morning, everyone. My name is Jay Wish and although I was introduced as President of Networks 9 and 10, my day job like Dr. Burkart is as an academic nephrologist, Cleveland, Ohio, taking care of patients. I have been involved in the ESRD Network since 1980 and this has fostered by evolving interest in quality measurement and oversight of dialysis. I'm past president of the form (phonetic) of the ESRD

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Networks and I have been chair of the ESRD Clinical Performance Measures-Quality Improvement Committee since its inception.

I believe the current system of ESRD reimbursement is broken and needs to be fixed, especially with regards to the alignment of incentives. An expanded case-mix adjusted bundle is a start in that

direction but I think it's only a start and still doesn't necessarily align facilities and physicians and current Medicare law does not allow for the mingling of Part A and Part B funds to reward dialysis providers that decrease hospitalization costs. Nonetheless, we all share the hope that a properly designed and implemented case-mix adjusted bundle will have the desired effect of increasing system efficiency without sacrificing equitability.

As far as the first question is concerned, what do I hope this payment, expanded bundled system will accomplish, I think the expanded bundle will eliminate the perversity of the previous system that forces facilities to lose money on the composite rate

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so that their only profit center is injectable drugs. The current temporary average acquisition cost fixed for the system will not eliminate the injectable drug profit center for the 50 percent of mostly larger providers whose acquisition cost is less than the AAC and will unfairly penalize the 50 percent of mostly smaller providers whose acquisition cost is greater than the AAC because of their lack of purchasing power.

For that second 50 percent, there may be an incentive to seek less costly and possibly less effective alternatives to the injectable drugs in order to remain fiscally viable in an increasingly LDO-dominated industry which may adversely affect patient outcomes. An expanded bundle makes the injectable drugs a cost center for all providers but eliminates the clear-cut loss that smaller providers will perceive in the AAC system and therefore depending upon the scope of the bundle will promote patient care based on best practices rather than profit motives. This should ultimately benefit patients, especially those whose case-mix reimbursement level is attractive

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to the providers.

The question about what are the downside risks of expanding the bundle, I think that access to care and patient-centerness are in greatest jeopardy in expanded bundle. Even with case-mix adjustment there inevitably will be patients whose costs far exceed reimbursement and providers may have a low threshold for adversely selecting such patients, so-called cherrypicking. Facilities in which the case-mix is

financially unfavorable and they close entirely affecting access to care and overburdening nearby facilities that may already may be operating at thin margins.

Patients who choose to be nonadherent even with appropriate education and resource allocation will adversely be selected because of higher costs and higher -- ACO (phonetic) rates. The availability of resources at the facility level to promote patient-centerness through education and rehabilitation will be strained as margins decrease.

The question about what three key features

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should a bundle payment system have, the first would be a sound case-mix adjustment methodology that uses patient level data which is cost linked to outcomes rather than facility cost reports as the most recent iteration dependent upon. This will require a robust -- as Dr. Burkart pointed out -- data collection and analysis infrastructure that addresses process measures as well as outcome measures.

The second would be features that support patient-centerness by providing resources for education and rehabilitation for patients at risk for not-adherence and as a result for adverse outcomes. And the third would be alignment of incentives between all providers, physicians and facilities with, as I said before, possible rewards for Medicare Part B from funds in savings in Part A.

The fourth question is what key features should the bundle payment system avoid. The first would be failure to account for patient center benefits of local facility ownership leading to what I call the "Walmartization" of the dialysis industry. The

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economies of scale offered by the large dialysis organizations may be attracted to Medicare in terms of system cost but bigger isn't necessarily better. Society has bemoaned the loss of personal service offered by the "Mom and Pop" retailers displaced by the big boxes. Independent dialysis facilities and the small regional chains may provide quality of life or patient satisfaction benefits that justify their higher costs and which must be measured before they are discounted by a "one size fits all" payment system.

The second feature to avoid would be

emphasis on outcome measures over process measures since process is more clearly linked to costs and can be supported by best practices and other evidence. Although some outcomes such as catheter use and hospitalization can be linked to cost as well, it's ultimately the continuous improvement and practice that will lead to cost savings and better outcomes.

And the third thing to avoid would the failure to hold all stakeholders accountable with emphasis on the dialysis facility as the sole target

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for cost containment and performance measurement. Nephrologists, vascular access surgeons and patients themselves influence outcomes based on their decisions and should be engaged in the alignment of financial and quality incentives.

And, finally, how can or should pay for performance targets be incorporated in the bundle payment demonstration, I think that payment-for-performance is a sound concept but premature implementation may obscure the validity of case-mix adjustment in our demonstration and therefore payment-for-performance really should be considered as a separate issue. It requires case-mix adjustment beyond that for a fair bundle payment and has even greater implications for adverse patient selection and loss of patient center care.

Payment for performance also requires even more alignment of incentives and greater accountability by physicians since their decisions will affect facility performance. Payment-for-performance necessitates more rigor in performance measurements

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which requires time for the measures to be taken, pilot tested and validated according to AHRQ guidelines and if payment-for-performance is incorporated into the demonstration, it must be done in a manner that is transparent, reproducible and generalizable. Thank you.

MR. AUGUSTINE: Thank you, Dr. Wish. Bonnie?

MS. GREENSPAN: I am Bonnie Greenspan and I am a nurse. I was nominated by the American Nephrology Nurses Association to participate in this program. I have been a dialysis nurse for 30 years and I have, in 1974 I started in dialysis, 1980, I opened a facility

which, opened my first facility which after five acquisitions by increasingly large dialysis providers gave me in '91, 70 dialysis facilities programs in New York, Maryland, Virginia and D.C.

And I have loved organizing care. It was always my first love to organize care so that we made it as easy as possible for people to do things right. And that is where I join with most of the people on

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this council in saying that perhaps we are broken in that and I think too much of what is a wonderfully valuable commodity, that being nursing time, is spent managing a biological rather than managing a patient and that's because it accounts for so much of the margin of our viability as facilities. And I think somehow the new organization has got to expand that focus so that nurses can perform the way they need to perform in our facility.

In the interest of being able to organize care better, in '89 when I gave up and said I cannot spend a dollar twice, I went back to Wharton because I thought those people knew how to do that and I graduated and realized that they don't know how to do it but the thing they do know is how to look at the ways that were absolutely terrifying me as each new wave of challenge hit our industry. I learned to look at it more as something that you learn to get out there and ride those waves.

And that was part of what I think we need to do now is to say that in every time of crisis

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there's an opportunity and we need to find the opportunity here to open up the possibilities for giving our patients the care that the government has charged us with providing to them in some new ways, which brings me to the questions that you specifically asked me. What do I hope for it? Well, I think that patients and providers all have exactly the same hope. They want to survive.

So, I think we all have that as in common and I think to that end that my hope is that whatever evolves from this study is that, this experiment, is that it is sustainable, a sustainable program which is really critical important to us, that it minimizes risk because capital is very important in the technical programs that we run. Just for safety, the equipment,

the environment, it requires a lot of capital and we need people to still feel that they can put that capital in.

And if it does seem unclear and risky, we're going to have to provide returns that are unmanageable in this kind of an industry, especially

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where expenses are tough and margins aren't great. So the more we can make people feel there is less uncertainty, there's less risk, the better we are going to have people keep investing the capital that we require.

And then the other thing is that I think that we need to make sure that we to the extent that we can do what everybody else wants which is align our quality and our reimbursement well enough that we don't end up spending the therapeutic balance of our patients in some way that was not intended.

The downside risks, I think that the main downside risks are the potential for people who can't figure out a good way to provide both quality and make a good return to settle for the return, since it's complicated to do both. I also think that the other potential problem is confusion, which makes it harder for nurses to focus on the areas of care that they require rather than easier.

The three key features that I think that it should have is it should be straightforward, it should

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be sustainable and I think it should be outcome-sensitive with real outcomes as everyone has addressed ahead of me, the outcomes that really matter. And there was a study, I don't know if you guys have heard about it, I tried to get some real information on it but they spoke on the radio the other day of a study that had been done on happiness for dialysis patients. Have you heard of this study?

There's a study on happiness. They gave people Palm Pilots who are dialysis patients and nondialysis patients and they asked them if alarmed at a certain time, you check in and answer certain questions to see how happy you are and comparisons show that dialysis patients and nondialysis patients, just general population, were equally happy.

And I'm not certain that prior to the time when we used the aggressive measures we do now, I have

been, as I said in dialysis 30 years and the patients that I've cared for with hematocrits of 23, were not as happy as the patients, as the population that was not on dialysis. I hope we don't lose that.

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I think that though some of the things like employment and other issues we've tried to track are not as compelling as you would think they were for the therapies we have been involved in for the last, increasingly over the last twenty years, that there is some evidence that the patients feel better. And I would hate to think that we're going to sacrifice that while we're still collecting data.

The key features for the bundle that they should avoid, financial reward for poor care, distraction and not having a reasonable way to judge performance level. I think that's one of the things that I am concerned about, just setting it up and having no safety net at all for decreasing performance.

And, pay-for-performance, the main thing I'm concerned about there -- and I do have some concerns about that -- are that the performance measures are meaningful and also that the measures that we use address improvement and not just absolute figures because we don't understand why some places have a very difficult time getting their measures up

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and so we want to be able to continue to incent these people rather than having them bail and it seems like making improvement a reward factor would be important.

MR. AUGUSTINE: Thanks, Bonnie. Dr. Eggers?

DR. EGGERS: Paul Eggers, I've been at NIH now for a little over four years. I'm responsible for the operation of the United States renal data system. I'm also a co-project officer on the data dialysis trial, which actually we do hope will be in the field sometime this year. And one of the more interesting things we're doing nowadays I think is expanding our research into chronic kidney disease as, because we have, ESRD has been under the street light. We have been looking at it, been there for a long time and in the last two years we've realized that much of the problems is of course in the CKD world.

Before that, I was at HCFA for 22 years in the Office of Research all that time in which I did a

lot of the research in the area of ESRD including financial research, which is undoubtedly why I'm here.

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One first statement on the issue of happiness, I'm glad to hear that that study came out. I'm sure that Roger Evans would be very, very happy at that result because that's exactly what he found 25 years ago when he did his initial studies on that.

I only have four points, two of which are highly repetitive of what the people have said. When you get this far around the table, it's hard to come up with something that hasn't already been addressed. But my first three words were, do no harm and the corollary of that is an old aphorism, if it's not broken don't fix it, and, I would actually say also in relationship that if it is broken, fix only the part that's broken. And perhaps that's because I was thinking of Social Security.

Anyway, moving onto my second principle which everybody has already said is fairness and however we define that it should be with respect to obviously the government and providers, however they're identified, and also to obviously the patients. The only two points I have which may be at all different or

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in some ways additive to what's already been said is on the issue of the bundled payment and the flexibility therein, and also I'm going to talk a bit about case-mix.

I conceive of payment policy as running a continuum from a full fee for service to a full capitation type of payment. And, if you think about those two extremes, the incentives there are much different, obvious, and they have both positive and negative consequences. A full capitation in principle is an exceedingly nice situation because you are free to give exactly what the patient needs and bill exactly for what the patient needs and no, nothing else, and therefore the system in optimal situations should work perfectly well.

As we know, it doesn't and patients get a lot of the things that perhaps they don't need. And so we think of efficient system as perhaps moving all the way to a full capitation system. And what do we have in a full capitation system? Well, hopefully an amount is given to a provider or an insurance company or an

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HMO or something and they have the flexibility to use that money in the way that is in the best interests of the patient. And that again is theoretically a very fine sort of unit.

As we know, the problem there is under-service because it's easy to take the money and run. And, in some sense that's kind of what happened in the initial EPO payment in which it was essentially a capitated payment and patients were underdosed. Now we've moved to a system in which we pay by the amount of dose, which is a fee for service kind of thing and now we're worried about more risks than are necessary and of course that's tied in with the whole payment policy as well.

So, my point is that a bundle payment falls somewhere in the middle on that. Okay? It's not full capitation. It's not fee for service. It has little bits of elements for both but it also has getting to the problem of what are the downsides. Insofar as it puts things together, it gives more flexibility; that's a good thing. It also raises the specter of

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underservice. And, I don't want to say any more about that but it's a continuum here and I think we should always bear that in mind.

With respect to case-mix adjustment, in some sense my comments are a little bit similar there. I believe that case-mix adjustment has become almost a holy grail in the medical world these days, and it works I think very well in the area of the prospective payment system for hospitals and also it obviously is needed there in Medicare Plus Choice. But there's this idea that it always works and it's always a good thing. It has downsides.

To the extent that you're moving towards the fee for service continuum of the end of that continuum, payment continuum, it becomes less and less necessary. The extreme example I use is flu shots. We do not case adjust flu shots and nobody thinks that we should adjust, case adjust flu shots because it is a very simple procedure and we don't think that it should vary and so on and so forth.

At the other extreme, we do think that you

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case-mix should adjust full capitation. Where does the

bundle service fit in there? Well, I'm not exactly sure and I hope to be informed today by the KECC people on that because we do have a service here which is in some sense a routine kind of service in which everybody gets more or less the same kind of service here. Now, to the extent that the patient varies, and that is significant across facilities, there is a need for case-mix adjustment.

However, remember the case-mix adjustment is not a perfect sort of thing. A, it won't perfectly case adjust for every single patient. It lends itself to a certain amount of gaming on the system and it is a burden as well. As we can see, there is information that needs to be provided in order to adequately case-mix adjust and so on and so forth. So it's not as though a case-mix doesn't come without some burden associated with it.

And, so, I think there you have both the upside and the downside. It does allow for the specific kinds of groups of patients which will be more

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difficult to take care of. You know, not surprisingly, dialysis facilities are like hospitals. They suffer from the Lake Woebegone effect. They all believe that, you know, theirs is above average in terms of case-mix and it turns out that, you know, when you average across it, half are on this side and half are on the other side. So -- huh? My patients are always sicker. That's true. That's a universally held sort of thing.

So, those two things that, you know, we are on a continuum here of capitation; it has both the pros and the cons and we have looked at both of those and secondly, personally, I am less enthused with the wonderfulness of case-mix adjustment in all cases and I think we need to be aware of that.

MR. AUGUSTINE: Paula?

MS. CUELLAR: My name is Paula R. Cuellar. I have been a registered nurse since 1972. I completed undergraduate curricular programs at Purdue University in West Lafayette, Indiana, and the College of Mount St. Joseph at in Cincinnati, Ohio. I have completed classes toward my Masters Degree at Ball State

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University in Muncie, Indiana. I have a varied background in nursing but I have been actively involved as a renal nurse for over 25 years. My current

position of Care Center Director for Dialysis at the University of Chicago is the equivalent to a Renal Administrator.

The University of Chicago Hospitals dialysis program is a hospital-based program. It is fully hospital owned and operated. We treat approximately 450 patients with ESRD. What do you hope payment based on an expanded bundle accomplishes or achieves? A proposal that is complete and acceptable to all parties involved, based on best evidence available and actual costs of providing care. Reasonable expense to the taxpayers that will assure that quality is at the highest level and that potential for technology and research advances to move forward. Yearly updates provided as for other Medicare programs, For patients, access to quality therapies for all patients -- measured and reported timely for beneficiaries and taxpayers review, an appropriate

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case-mix adjustment to prevent adverse patient selection bias.

Among the adjusters -- I have a question-- would economic factors be part of the adjustment? Do indigent patients need to be considered for increased resources to assist with issues such as transportation, housing, utility cut-offs, poor access to necessary medicines, et cetera, that all seriously impacts their health and quality of life.

For the providers of the facilities, fair opportunity for all providers, recognition of special considerations, not just rural vs. urban issues but also chain providers vs. non-chain small hospital-based, compare all the outcomes and the mortality rates of those providers. Research and technology advancement participation, providers in remote locations with little opportunity for quick adjustments, to issues.

An example is the Pacific Islands, where there's very limited access to resources, even greater limitation than that experienced by the rural

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providers, Disparate opportunity for home therapies and appropriately stimulate that opportunity. Address the issues of the appropriateness of care, quality of life issues.

I mean, the cost report data that we have,

I don't see, don't necessarily think that it reflects the true cost for the dialysis program of everything that's included. Access to ancillary caregivers should not be restricted unnecessarily if the intent is to centralize more care with the nephrologists. The MCP will also need to be addressed. Could other physicians or caregivers such as podiatrists see the patients in the dialysis and be able to bill for that care? Allow for staffing for nurses to properly assess the patients.

An example is the diabetic footcare checks and patients with vascular disease to check and make sure that there's people who are being properly assessed and avoid the crises situations. What are the downsides of expanding the bundle? Assessment of disabilities, specifically would like to compare the

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case-mix between home programs and other programs, could more beneficiaries be able to go back to work and not be drawing on disability? Cost containment can have an impact on reducing staff and hence quality in the lack of patients.

The key features that I think need to be in our bundled payment system is attention to areas with the most potential for improving the care and quality of life, impact of other care to the patients, and again that's repeating, are we providing ESRD care or are we providing total care for the ESRD patient.

What three factors should be avoided? I'm concerned about how we will handle hospitalizations and hospitalizations that are not always listed as other than overnight stays or with 24-hour stay. Capitating the vascular access surgeons might be risky, unduly restricting the MD's ability to tailor specific situations to the patient, coordinating care of the patient with other physicians such as the endocrinologist, podiatrist and vascular surgeons.

For the pay-for-performance, assure that

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there's no fudging of the numbers to enforce it. An example that I can think of is on lab day the patient runs as full time and the rest of the month the patient runs much less of the time and use the outcomes rather than the absolute figures.

MR. AUGUSTINE: Thank you. Nancy?

MS. RAY: Hi. I am Nancy Ray with the

Medicare Payment Advisory Commission, MEDPAC. MEDPAC is a small congressional commission. I'm one of about 20 policy staff analysts there. MEDPAC is charged with advising Congress on issues relating to Medicare payment, Medicare beneficiary access and quality of care. I'm one of the staff people that helps support our 17 commissioners.

Our commissioners meet seven times a year, at a public meeting in Washington, D.C. where they deliberate and make recommendations to the Congress. Both MEDPAC and one of its predecessor commissions, PROPAC, has a long-standing history of advising the Congress on ESRD issues. We're fairly well known, I guess, for our annual payment update recommendations

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for the composite rate. We are legislatively charged to make that recommendation to the Congress each year and that's published in our March report which is available up on our Web site.

Beginning in March of 2000, and then we started an analysis looking at the outpatient dialysis payment system, and it led to a series of recommendations that we published in our March 2001 report to modernize the payment system, including broadening the bundle and adjusting payment factors that affect providers' cost. We reiterated these recommendations in an October 2003 report and in that report we also talked about the need to collect quality data and to continually measure quality when the payment bundle is broadened.

In its March 2004 report, the Commission made a recommendation that the outpatient dialysis payment system, that payment should be linked to quality for both providers, facilities and physicians that treat dialysis patients. I won't go into all the specifics right now of our recommendation but it

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included rewarding providers both based on quality attainment and quality improvement.

I won't go over all the questions because a lot has already been said by my colleagues. I think the three key features that a bundled system should have is -- and I think it's a point picked up by Bill and also by Paula -- I think it should include, well, MEDPAC is on record for it to include services commonly furnished to beneficiaries. And I think some thought

needs to be given to including services also commonly needed by beneficiaries including Medicare preventive services. A majority of patients are diabetics and I think some thought needs to be, we should have some reflection on including the Medicare covered diabetic services, for example, in the broader bundle.

I think the second key feature of a bundle payment system should be that it adjusts for factors that affect providers' cost. Case-mix has been talked about. It should also accurately adjust for differences in labor cost, for example. And I think the third feature is the again going back to MEDPAC's

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recommendation that payment be linked to quality, that the bundle payment provide system provide incentives for providers to maintain high levels of quality and to improve their quality. And then, again, skipping to the last bullet point, how can a pay-for-performance concept be incorporated? I think that that's something that we need to discuss here but should it? Yes. Again, the Commission is on record for that. Thank you.

MR. AUGUSTINE: Thank you, Nancy. Last but definitely not least, Dr. Lazarus.

DR. LAZARUS: Well, with the privilege of being last, I'll try to eke out something here to say. I'm a nephrologist. I am a nephrologist. I have been a nephrologist since 1969. I taught at the Harvard Medical School and the Brigham and Womens Hospital, ran the nephrologist program there, had a large private practice. In 1996, I came to my current position in the hopes of being able to positively affect patient care in a large number of patients.

I'm going to answer these questions, one in

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order, and, basically read my responses to get through this quickly. What do I hope the bundle will accomplish? For ESRD patients a more cohesive, integrated, appropriate improved care. This should be the first step in moving towards a complete disease management approach. It is not but it should lead to that. For providers, I think it will hopefully offer a simpler system that is cost effective and rewards for patient care.

I believe the system will likely improve the work environment for nursing staff. We have a

problem with nursing shortage, nurse turnover, and I think getting nurses more involved in the total patient will be a real positive for nursing staff. This demonstration should align efforts and incentives of nephrologists and providers, wherever possible, is mandatory to do that. We must carefully consider whether this is a single dialysis bundle or a bundle of monthly services. This was discussed at the PPS technical expert panel and I think we came to a conclusion that they are totally different bundles and

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we must carefully consider which one we want to do.

One of the downsides of a bundle, well, bundling could possibly drive providers to attempt to use fewer resources. Payers can also ratchet bundles downward. This must be discouraged so as to avoid erosion of provider services. Appropriate and well-defined clinical quality outcomes must be identified and mandated -- otherwise that will happen -- to eliminate the possibility of reduced quality of care.

If reimbursement is not appropriate or if this demonstration is used to reduce costs too aggressively, then the demonstration will fail and an opportunity will be lost. CMS should consider funding part of this demonstration from Part A which will benefit from the savings created. There must be provisions for inclusion of new dialytic, diagnostic, pharmaceutical and safety improvements as they come along.

What three key features should the system have? Quality outcome measures, I think you have to do

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that, and it must be based, despite what Paul said, I believe on some clinically correct case-mix adjustment. If we don't case-mix, there will be cherrypicking; sick patients will be excluded from this process. Now, it may be something as simple as an acuity patient scale determined by a nurse and a doctor in the dialysis unit but we must have some sort of adjustment.

There must be appropriate resolution of the patient, secondary payor payment component. The first demonstrations, as Bob mentioned, failed in two of the demonstration sites and will fail again unless that 20 percent is dealt with. And finally, there must be an annual update in this demonstration.

What three key features should a bundled system avoid? Again, adverse selection due to inappropriate incentives and lack of proper case-mix adjusters. I think that is a danger. Failure to include all patients who participate in facilities. I mean, you cannot manage patient care when half your patients are in this demonstration and half are not. For those facilities that will participate in the

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demonstration, I believe it has to be 100 percent of all patients participating. I don't believe you can deliver care with two different systems.

Inadequate reimbursement based on outdated dialysis cost -- this has been mentioned before -- and our economic data from sources other than independent dialysis facilities, you cannot take physician office data and hospital data and apply it to dialysis units, I don't believe. How can or should pay-for-performance concepts be incorporated in the bundle payment demonstration?

We must establish easily measured and appropriate performance outcomes that relate to the bundle and for which there is room for improvement. We must utilize clinically correct case-mix adjusters -- clinically correct case-mix adjusters -- not based on current dialysis facility cost reports. That is the wrong source of data for case-mix adjustment. Reimbursement should be more focused on an upside for improved performance rather than a penalty for poor performance, withholds and earn-backs. Reward only

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improvement at first to float all boats before penalizing those on the low end of the performance criteria; determine whether payment will be made for reaching set targets or exceeding them or making improvement in one's own performance history. Thanks.

MR. AUGUSTINE: Thank you, Dr. Lazarus. We have a few minutes and we'll take a break at quarter till. I do want to make a few summary statements. I feel like the editor of a book with ten, eleven really well thought-out chapters. I will say I am here not as the senior executive of the ESRD program. I am here as a member of the community. And, from working in the community and working at CMS, I want this to work and I think, I believe we have all stated we have the same goals of improving the payment system that we have,

such that we get the most value for our money and improve care as best we can and that it's fair to providers as well.

I do want to make a few comments. CMS is quite interested in this to allow as to provide some additional flexibility. We realize that right now a

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lot of our policies influence practice patterns and believe that, you know, a lot has taken on decision-making ability of individual practitioners. And, for example, the example given of paying on a monthly basis as opposed to a per treatment basis could allow innovation and new technologies.

For example, daily dialysis, if it's a decision of the patient and the carrier would do so it would be quite helpful in spurring those activities. Personally as partly an economist I believe there's a lot of ways to insist maybe not in meds, maybe more just in resources, the nursing time, which is extremely valuable, two of the break-through initiatives we have at CMS presently are improving turnover rates and continuity for nurses in various locations.

And, one last, as far as case-mix is concerned, Paul, from the way I have always viewed case-mix, doing a lot of statistical work in my career is that case-mix will never be perfect. At best you usually get up to 25 percent, and that's actually a very good case-mix. It's usually closer to 5, 10

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percent. But the way I look at it is you're trying to explain variation and explaining 5 percent is kind of like a glass, having a glass that's that full as opposed to a glass, it's better than a glass that's completely empty.

And, so, you are explaining something. It may not be enough or may not be everything but it's better than nothing. And also in working with communities developing report cards and whatnot, case-mix is very important as far as helping people buy in and hopefully averting as much cherrypicking as possible.

I do want to talk a little bit about some of the work that CMS has been doing. We have been talking a lot about infrastructure. Dr. Wish and the Networks have been providing a lot of support to CMS. We realize that we need some good infrastructure in

place to move forward. We have been working on the core dataset. We have been working on the CECS, which is the Consumer Experience with Care Survey. CMS has been sponsoring that activity with ARC. As well we

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have this, the clinical performance measures which are kind of the envy of the industry.

There's a lot of work right now on performance measures but in ESRD we've been doing it before anyone else. CPMs have been around in one form or another since 1994 and even predate HEDIS, which I like to brag about around the agency. Envision in the core dataset our major activities which are going to help us gather the information that's needed, the patient level to make case-mix. The cost reports are inadequate. I mean, they're good enough, we have to use them but patient level is the best type of information to use. We're working together to try to gather that information. As well as CMS has made an open offer to working with the community on revising the cost reports as well.

One last caution I do want to make is when we're talking about case-mix we need to differentiate whether we're talking about cost or about outcomes because the case-mix would be different for each. What predicts how much resources we use and what critical

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outcomes you get are very likely different things even though you would like to think they are correlated.

And finally, everyone spoke very ambitiously in this group. I want to make sure, you know, we don't set unrealistic expectations. We are trying to improve the system. We're not going to fix the system. There is no perfect payment system. Our charge is to propose an alternative, an experiment, if you will -- from Dr. Rubin's comments -- that we'll be able to learn from. What information do we need to go forward? But, I don't want people to think that we have to fix everything. There are risks we'll have to live with and that's what we're going to have to discuss and talk about and weight together. So, thank you. We will meet together at 11 o'clock, we'll reconvene. Bob, do you have any comments?

DR. RUBIN: No.

MR. AUGUSTINE: Thank you, everyone.

(There was a break in the proceedings.)

MR. RUBIN: We're ready to get started. If the committee members could come back and take their seats, we'll try to stay on schedule. All right, everybody.

MR. AUGUSTINE: We're getting ready for the next presentation. If everybody can take their seat, please. If we could go to the next slide, please. All right. We're now going to have a presentation of Lana Price, who is going to spend just a few minutes providing us with a CMS perspective on the past, present and future of the composite rate system. Lana?

MS. PRICE: Okay. Good morning. I don't know if everyone is here. Is it okay?

MR. AUGUSTINE: Yeah.

MS. PRICE: Okay. Can you hear me? Is that all right? Okay. The purpose of my presentation this morning is to set the context for the rest of today's discussions by addressing the composite rate payment system and how it has evolved over the years or I should say how it has not evolved over the years so that we can start with where we are today as a basis for moving forward to approve the ESRD payment system. As most of you probably know, the composite rate system was established back in 1983, which is over 20 years ago.

And, up until the recent MMA provisions, it has been virtually unchanged since that time. In addition, the updates to the payment rates have been very limited. The only adjustment currently made to the rate is the geographic adjustment, and I'll have to admit it is an outdated one at that. The payment rate is based on a specific bundle of items and services related to dialysis treatments and represents payment for outpatient maintenance dialysis, hemo or PD, in a dialysis facility or in a patient's home. The bundle includes all patient care services, such as nursing, nutritional counseling, social services, care planning, et cetera, in addition to the actual supplies and equipment related to the dialysis process. Also included are specific drugs and labs.

All of the medically necessary drugs and services provided through ESRD facilities are separately billable. Over the years, facilities have been able to increase productivity as a means of

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keeping composite rate costs down; however, in recent years, productivity gains have leveled off to the extent that composite rate payments have not kept pace with increasing costs.

As a result, ESRD facilities are finding it more difficult to maintain profitability. Payment for separately billable drugs and services has continued to grow and currently accounts for over 40 percent of Medicare revenues to ESRD facilities. According to facilities, the margins on separately billables have historically subsidized shortfalls in composite rate payments.

Next, Medicare Modernization Act or MMA makes some significant changes in the way Medicare pays ESRD facilities for dialysis services and separately billable drugs and biologicals beginning in 2005. It is important to note that the MMA provisions did not change the current bundle included in composite rate. The legislation increased the composite rate by 1.6 percent. In addition, the MMA made two budget-neutral changes to the ESRD payment structure. They're
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intended result in more accurate payment for separately billable drugs and dialysis treatments.

First beginning January 1, 2005, payment for separately billable drugs is now based on acquisition costs rather than average wholesale price. Payment for EPO is also set at average acquisition cost. The statute also provides for an adjustment to the composite rate to add in fact the savings from the drug payment changes into the composite rate payments for dialysis treatments; therefore, the composite rate was increased by an additional 8.7 percent beginning January 1, 2005.

Second, the legislation required the establishment of case-mix adjustments to the composite rate based on a limited number of patient characteristics. Because there is no data available at the patient level with respect to the use of composite rate resources, we had to develop case-mix adjusters based on the effects of certain patient characteristics on average facility level composite rate costs. Through regression modelling we identified three
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patient characteristic categories that influence

facility level costs.

Those include five age groupings, low body mass index, or BMI, and body surface area, or BSA. The adjustment based on body mass index would apply only for patients with low BMI values defined as 18.5 kilograms per meter squared, which is consistent with the NIH and CDC markers for malnourishment. The BSA adjustments apply to all patients other than pediatric patients. And this adjustment is set at a reference point of a 1.84 BSA which represents mean BSA for all ESRD patients in our database. In other words, the adjustments for patients with a 1.84 BSA is set at one, and would vary from that point with the largest adjustments being made for patients having the highest BSA values.

In addition, we established a separate case-mix adjustment for pediatric patients, those under 18 years of age, and this adjustment is intended to recognize the unique costs associated with the treatment of younger patients. All of these case-mix

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adjustments will be implemented April 1, 2005.

Our analysis of the impact of the case-mix adjustments indicated that they would have limited redistributional impact on facilities since the distribution of patients across facilities is relatively uniform. It's important to understand that our ability to develop more precise case-mix adjustments for composite rate services is hampered by the data limitations with respect to the variations in resource consumption at the patient level. This is not the case for separately billable items and services since they are individually identified for each patient through our billing system.

Our goal is to continue refining the basic case-mix measures as more data become available in the bill such as current height and weight. To that end, we are encouraging facilities to begin reporting relevant comorbidities on their monthly bills so that we can better assess the impact of certain comorbid conditions on composite rate costs.

In addition, the statute gives us authority

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to revise geographic adjustments currently in effect and requires that any new geographic adjustments be phased in; therefore, for 2006 our plan is to revise

the wage data and labor market area definitions based on the newly established CBSAs, core based statistical areas. And we expect to issue a proposed rule in early summer.

So, that's the current ESRD payment system in a nutshell. It's lasted this long so you might have ask, so why change it? In actuality, the current system has many shortcomings. First of all, the bundle was old and may not reflect current medical practices. Are the components of the bundle still relevant today? We really don't know the answer to that question since we do not collect any data regarding which composite rate services are actually provided today.

Second, there is no update mechanism nor is there a mechanism for recognizing technological advances. Cost-saving technologies in dialysis treatment have been readily adopted, such as reuse and high-flux dialysis machines as a means of increasing

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productivity; however, new technologies that increase costs are not readily adopted because the composite rate system is not set up to deal with new technologies that replace items currently covered in the bundle.

Separately billables have grown significantly over the years and with that come the inherent problems of dealing with inconsistent medical review policies. This has been especially true with separately billable lab tests. Probably the most fundamental shortfall of the current system is that it does not give facilities the flexibility they need to provide appropriate care for its patient population. The coverage and payment rules have become so complex that it interferes with the day-to-day business of caring for patients when the clinician needs to worry about the payment implications of care.

As we work towards improving the payment system for the future, we must think outside the box. This demonstration provides a unique opportunity to test innovative approaches to payment. Of course, as I see it the challenges will be to get the bundle payment

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amount right, to ensure that sicker patients get paid appropriately through case-mix adjustment, establish an update mechanism so that the payment system can evolve with changing medical practice, and, most importantly, hold facilities accountable for good patient care while

rewarding those facilities that achieve exemplary outcomes. Hopefully, through this Advisory Board and the demonstration process we can work together to achieve the best payment system that will work for facilities as well as beneficiaries.

Finally, with respect to the report to Congress that we will be working on, which is due October of 2005, we believe that it's important that the demonstration project and our recommendations concerning the design of a bundle payment system are comparable. And to that end we hope to gain insight from this Advisory Board as we develop our recommendations to Congress. That's it.

MR. AUGUSTINE: So far we have heard from members of the board and we have also heard from CMS concerning the opportunity to have an IRISS (phonetic),

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that we all share a limited bundle payment system. Go to the next slide. We're going to talk about the vision of the quality parameters and also we're going to have a data preview from Kaye (phonetic). So the high-level goals for any prospective, any payment system really are very easy to agree on, to try to improve quality and efficiency.

Historically, Medicare has paid for what is done for patients, or a more utilization type approach, services and procedures. It does not base payment on the outcomes that are achieved for patients. The recent thinking, however, opened the possibility of introducing pay-for-performance as the new buzz-word at CMS and around the Beltway, by introducing pay-for-performance notions. And this is a topic we will spend some time discussing not so much at this meeting but in future meetings.

So, translating our general overall goals into a little more specifics and more challenging language, it's a payment system that create incentives to reward efforts, a word that was used around this

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table, value, which is a recognized value, to improve the clinical management of patients. It should also create incentives to improve the efficiency in which dialysis is provided.

And finally, it should create incentives to treat patients with the greatest needs, or at least not punish those facilities that treat the most complex and

severely ill patients, or, as described by many at this table, we all share as a concern is cherrypicking. Next slide, please.

As far as quality is concerned, I think this is pretty well recognized by this community. I always refer to it as Triple A, adequacy, access, area (phonetic) management, and then you've got mineral, metabolism as well as the main four areas of quality within the ESRD; vascular access is a major initiative for CMS, which is the first. There are not too many days I'm not happy about the teamwork and the leadership that the community has taken with regard to this approach.

And it's one of the things that is under my

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charge in my new role so I get to hear all the good news on a regular basis, so I can still feel close to this community. As well, there are other items we may need to look at. And when we were talking about flexibility earlier this morning, for example, with nutrition and with access, in a more flexible bundle environment, you may want to provide perinatal nutrition or therapy or you may want to provide access to monitoring, and it may be in your financial best interest to do so, may be in the best interest of the patient to do. And, so, that flexibility doesn't exist in the current system, which may be able to exist in the system that we work together on.

Also I do want to make a point as we've discussed more and more about pay-for-performance and this is a major initiative of this, our current administrator, he has been very clear that he believes that the current system, Medicare at large is broken and that we pay the same for someone to provide the service whether or not they provide it well or not, is not a very good economic use of limited resources. It

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gets back to discussion that, you know, echoes a lot of comments today about value.

But as we talk about pay-for-performance, we need to make sure what we're measuring. That also echoes our comments this morning, process versus outcome versus patient-centerness versus structure. These are all areas that are important. You can't just use outcomes because outcomes tend to be more touchy-feely and harder to measure. You can't just use

process because not all process measures are tied to outcomes measures, tightening enough to show cost benefit in a budget-neutral environment.

There needs to be additional measures for patient-centerness and that's why I'm happy about the caps initiative that will move us further along in that regard. And, structure as far as having EHRs, that's something that is of prime importance to this administration. And there are ways that we can provide incentives for people to have very well-designed electronic health records. That's something that we're quite interested in as well. So, a number of the

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opportunities requiring improvement have been identified and while we assess in the community we want to find ways in this demonstration -- and we'll talk about it more later -- about how we support those goals.

Next slide, please. And the design issue and this is primarily what we will be touching on today. We won't be finalizing any decisions but we'll start moving down certain paths which will be helpful in giving, taking some guidance about what type of follow-up we're going to need, plus continue down the road. The scope of payment, many of you have talked today about what exactly this expanded bundle entails, what responsibilities are at the facility level, what's the unit of payment, is it for treatment per week, per month; the case-mix adjustment, I believe we have heard plenty of discussion on that, input price adjustment, outlier circumstances, which we're all sensitive to, and especially, you know, hear a lot of discussion today about small facilities, what happens if there are a few patients that really blow everything out of the

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water. Large facilities can absorb that; small facilities may have a more difficult time. We need to recognize that.

Price updating, that's very important. New technology needs to be, well, I don't want to leave outside what's actually within the scope of our work today but there had been some discussions about a future payment system, about needing to incorporate new technology in price updating on an annual basis. Well, that's not really something that we're going to consider I believe in this demo but it's something that

you may want to have some input on.

And, finally, the pay-for-performance, which I think I've talked about enough this morning. With that, I'm ready to hand it over to University of Michigan's kidney epidemiology -- I remember -- or Tech for short. I remember working originally getting to know Bob, and Bob's not in his presentation but whenever I see Tech I also relate it to Bob. I still remember reading his original paper on SMRs and culling through a vast database to try to recreate SMRs by

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hand. And so I don't know if that's a good memory of you, Bob, but it was a good leadership, you know, it moved in the right direction and provides some leadership to the community. So, I thank you for that. With that, Tech, you can take it over.

DR. TURENNE: Thank you, Brady. I'm Marc Turenne from University of Michigan. I think we have two goals in this section. One is to briefly describe the data sources that are available, the tools that we have to try to address some of the issues that have been raised regarding what an expanded bundle might look like, and a second goal in this section is to give an overview of some of the data that we've been presenting throughout the day, in greater detail later, but just to give you a glimpse of what we'll be looking at today.

Next slide. In terms of the principal data sources that we'll be discussing, we'll be relying extensively on Medicare claims data, and as was noted, the services that are currently reimbursed outside of the composite rate system, fee for service type of

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reimbursement system, we do have patient level data on use of those services, through the Medicare claims. And so any data that would be used to identify what services could be added to the current measures and what case-mix adjustment might look like for those services that are added, there are patient level data available for that task. And that's again Medicare payments, the major focus for accomplishing those tasks.

As was also mentioned this morning, there are a number of different providers of care for dialysis patients, and based on the claims we can identify services that are delivered by not only the

dialysis facilities but a number of other providers of care, laboratories, suppliers, additional offices as well as other institutional providers. There are a number of other patients and facility level data that are available and those are listed there. We will be discussing some of these in greater detail throughout the day.

Next slide, in terms of the types of things

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that can be measured, here we're primarily considering what can be derived from Medicare claims, in terms of the types of services that are being provided, and, for the data that we'll be presenting today the major focus will be on the separately billable injectable drugs as well as laboratory tests that are also separately billable, various methods of utilization are also available from the claims data and different providers of care, many of which are listed here including different types of physicians that provide care to dialysis patients that may be useful in trying to determine --

(Brief interruption)

DR. TURENNE: That's good to know. What different types of physicians that are providing care to dialysis patients, as far as what their specialty is, whether they're nephrologists or other types of physicians or other providers, may be helpful in trying to determine what services that are being billed in the Medicare claims are most related to dialysis.

In terms of the characteristics of Medicare

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dialysis patients, there are a number of data elements. From the 2728 form, there's information collected from each patient as they start dialysis. There's demographics, comorbidity data also from the 2728 form, but this is supplemented with longitudinal data, or more current measures of patients status, in terms of comorbidity from the claims.

Using the claims data, the diagnostic codes that are the recorded on the claims, we cannot only identify those comorbidities that are reported at the start of dialysis on the 2728 form but also other comorbidities that might be relevant to the use of the injectables, the lab services or other services that we'll be considering.

DR. RUBIN: Could I just ask a question or

actually ask for you to amplify certain things? When you're talking, a lot of what you have talked about are administrative databases that more or less are publicly available and some of what you have talked about and I think will be talking about are databases that you constructed based on inputs that might not normally be

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available to somebody that was trying to, for example, replicate what you do.

So, if you could just indicate what are sort of KECC unique databases versus what are just government databases available to any taxpayer that's willing to fork over the money, that would be good. Because, I think that as you heard from the committee, data is a critical element here and it will be a critical element helping us to advise CMS as to what's going to be in here, and I think it would be useful to have some sense as to what has been particularly constructive to this project and others.

DR. TURENNE: Sure. It might seem to oversimplify things by merely identifying what the data sources are without really describing the effort and the resources that go into combining all different data that are available, not all of which are publicly available. Certainly the facility level data, for example, the cost report data, public use files, in the NEG, certainly there are more restrictions with regard to the use of patient level data that identifies

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individual patients.

I'm not privy to all the details on that as far as what kind of access research, what researchers, those different types of data, but there is no question that in pulling all of those patient level data together is an enormous effort. It's not something that -- it requires a great deal of effort, resources.

MR. AUGUSTINE: Let me echo Bob's comment. One of the major concerns I hear from the community is reproducibility, and training parenting and that's something that we're going to have to be quite cognizant of is when we explain things to the community.

You know, there's a number of, the belief is in the community that they can come up with the same datasets and bring them together through their analysis and try to come up with something that they feel like

it ought to be close to, at least close to what -- and we just need to be able to explain to them so that they can understand any discrepancies and if we all know all this practicing, not practicing, statisticians, that's

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part of the ethics of the good statistical practice is that you try to explain the caveats and data and what you did to it so if other people try to reproduce it so they can understand any discrepancies.

I can only guess that you take these datasets and you bring them to together and may massage them to try to improve data quality in certain regard and that may account for some of the differences. There may be others that we need to address, though.

DR. TURENNE: That's a very good point. As we move forward we will be careful to identify those types of issues as far as that affect how the data are used and where there are --

(Brief interruption.)

DR. TURENNE: I won't take it personally. We will try to make an effort to note those caveats and limitations where appropriate.

MR. AUGUSTINE: Okay.

DR. TURENNE: I that's think that's a very good segue into this slide.

DR. WHEELER: This slide.

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DR. TURENNE: A few of those, a few of the challenges or limitations in using some of these data sources would be listed here, especially those that are relevant. For those services that are billed by, sold by providers on the dialysis facilities, it may be difficult to determine what services are most related to dialysis and might be the strongest candidates to include in an expanded bundle, and we will see that later today because of the lab tests. And that may be done for a variety of diagnostic, may or may not be strongly linked to dialysis care.

Vascular access services are not always clearly identified using the Medicare claims data, and that has a lot to do with the procedure codes that are available to Medicare claims especially on the inpatient side. There are some procedure codes that do not allow us to clearly distinguish between procedures that either to place in initial access placement, to maintain an access or procedures that may not be

related to dialysis parts of this.
MR. AUGUSTINE: Mark, if I can real quick,
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if you could just for the purposes of people in the audience, they're looking at me, some of them are looking at me like they can't hear you, so if you could please speak up, I think the audience would appreciate it.
DR. TURENNE: And so that not, lack of specificity with some of the procedure codes and the Medicare claims data, may limit the extent that the current data can be used to identify specific vascular access services. And there is also the issue to consider that with that many of the vascular access services, especially those that are provided or including those that are provided on an inpatient basis, we are crossing over into other prospective payment systems that already reimburse for some of these services. That's just an issue to consider.
And in terms of the patient specific data, which include measures of utilization at the patient level, this includes payment data; however, it should be noted that these are payments and they may not reflect in many cases the actual cost of providing
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specific services.
Here we've listed a few notes about, that pertain to some of the tables and some of the data that you will be seeing. First, a definition -- I will just highlight a few of these. A definition that unless noted otherwise the dollars, the dollar amounts you'll be seeing in some of these tables are expressed in what is given the acronym MAC, allowable charges, maximum allowable charges under Medicare. This includes the patient cost-sharing obligation and so basically this means the 20 percent patient copay amount has been included for those services, where there is a copay.
Other things I would highlight, there are many different providers and suppliers for the laboratory tests, and, what we refer to as independent laboratories includes many, many of the laboratories that have an affiliation with a dialysis facility or a chain of dialysis facilities. Basically we're talking about laboratory, providers of laboratory services that may or may not be affiliated with dialysis facilities.
MR. AUGUSTINE: Let me just add, we were

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interested in that in the previous demo and when we went back and kind of looked at it, we found that just a rough estimate, about 90, at least 90 percent of all lab tests, both I think in volume and also in payment were for laboratory, done by labs that were affiliated with dialysis organizations. So, that was more than we had thought in the original demo but it's something that we learned in getting prepared for today.

DR. TURENNE: Thank you. We will discuss some of that in greater detail.

DR. RUBIN: Bill?

DR. OWEN: A query on the MAC, at 20 percent, is that treated as like an accounts receivable; the flip side of it is, do you know how much that 20 percent actually translates into women?

DR. WHEELER: We have not looked at that. I know that others have looked at that. We do not have that. Sorry. The answer is we do not have that information.

DR. OWEN: To either of the chairmen, perhaps later in the day we can have someone, someone

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here, either as a panelist or as a participant in the audience who might have information as to how much of that translates as, translates into bad debt, could address that.

MR. AUGUSTINE: I mean that, one of the things that we need to be aware of and they shift to an expanded bundle is our definition of debt, I mean, what can be included in bad debt changes. Currently, we only pay 80 percent of separately billable, do not allow bad debt for them because they're not as part of the payment system, prospective payment system and if we go to expanded bundle environment that other 20 percent could be potentially recaptured for bad debt. But as far as how much of that 20 percent we don't know specifically but we can ask and find out.

DR. TURENNE: There are also some details about the types of laboratory tests that are being identified in terms of the most commonly provided lab tests -- the top 50 is referred to here -- and also how some of these laboratory tests were grouped into clinical, broader clinical categories. These are

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details we will be discussing as we look at the data.

And here just a reminder again about the notation this afternoon that you will be seeing throughout many of the tables. At this point, we'll provide a preview of some of the data that we'll be discussing in detail throughout the day.

DR. WHEELER: Jack Wheeler from the University of Michigan. I have a quote here from Brady Augustine that I think is relevant. This is a "fast tour of some basic data" and that's what we're going to do this morning, and then this afternoon spend time going more carefully through some of the issues that arise from this quick tour.

MR. AUGUSTINE: Well, I wonder if it's notable or notorious. Thank you.

DR. WHEELER: Our purpose really in just a quick tour is just to give a common baseline to everybody of information that likely will stimulate your thoughts and discussions maybe even over lunch. This slide is indicative of a few things. One is it's just kind of the magnitude of the various component

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payments and also the fact that we have been tracking with a kind of a consistent set of databases for the last three years. And, and, so that's, that's just kind of the purpose of this slide. Just one note here, this slide applies to hemodialysis only and it is, facility, sorry, facility payments only. So, it's payments to the, or allowable charges to the facilities only.

MS. RAY: Excuse me. It includes freestanding hospitals?

DR. WHEELER: Yes, this is freestanding hospital-based facilities. Okay. This slide is meant to just give you a flavor, an indication of the kind of breakdown of Medicare allowable charges. And this slide is a little bit different in its source of information in that it includes payments for lab services that would go not just to the facilities but to independent laboratories as we have been talking about. So, just, I'm going to flip back. The previous slide indicates just payments to the facilities and you can see that the lab payments are very small and

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wouldn't even show up on the pie chart.

MR. CANTOR: Separate billables?

DR. WHEELER: Pardon me?

MR. CANTOR: Separate billables?
DR. WHEELER: These are, the separately billables are EPO, Iron, Vitamin D and other drugs.
MR. CANTOR: Separately billable lab tests.
DR. WHEELER: I'm sorry, separately billable lab tests. Thank you. So, when you include lab payments to independent labs, the laboratory size of the component of the pie chart starts to show up.
Note also that in this slide and in most everything we're going to be showing you for your use and consideration, the data are not going to be inclusive of nonfacility Medicare allowable charges, sorry, other than lab tests, that is, it will not include surgical services, imaging, et cetera, won't include inpatient services and importantly does not include physician and professional services. So, it's focused on the aspects of payment components that are subject to the new legislation.

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The previous slide was kind of an overall look. If we just zero in on what kind of drugs are included in the payments to facilities, principally to facilities, I should say, you can see that two-thirds of it is represented by EPO payments and the other components, Vitamin D and Iron or other major components along with EPO make up 98 percent or thereabouts of payments to facilities. And note also we have included in this slide payments to other suppliers of injectable drugs and those include sort of very few dollar amounts. So, almost all payments for injectable drugs go to dialysis facilities.
MR. AUGUSTINE: Do we include the DMERCs from like methyl-2 in here as well, the DME?
DR. TURENNE: No. We have included some of the injectables from the physician's supplier or from the supplier claims, which includes the DMERC for the methyl-2 patients. I don't know that they're all included yet but they are very small in terms of the percentages but we are in the process of fully incorporating those.

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DR. WHEELER: We can focus on lab tests, and this is once again a quick picture of a complex issue that we're going to be talking about in a lot of detail this afternoon. Quick picture, just to give you a sense of the kind of lab tests that are provided for

dialysis patients, and you can see kind of the breakdown.

Most of the tests are to evaluate Vitamin D, EPO, Iron, dialysis effectiveness, and hepatitis B. There are 8 percent that are for other conditions such as diabetes and they're included as well. We'll talk about the method we used to actually come up with this pie chart as a summary and give you some more detail this afternoon but this is a fairly detailed method for coming up with some, and this once again is sort of a picture of it that is kind of general.

DR. RUBIN: Dr. Owen?

DR. OWEN: The picture is cross-sectional. Are we going to see some longitudinal data this afternoon? I just don't remember from your slides. And the obvious reason I'm asking is that for some of

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these medications, and I likewise suspect that tracking with it, will be the laboratory test. These things are pretty substantial changes in terms of our ordering patterns in the last five years that we had at least observed through the CPM dataset.

DR. WHEELER: Right. Yes, we've seen different rates of change in these as well. Our slide presentation, I believe, is not very thorough in terms of giving you a picture of trends over time. The one, the one over-time trend that I have already showed you is kind of in the aggregate component payments; you can see our three-year picture. We have done a lot of work in our office in terms of looking over time and we can give you a lot of that information as we proceed.

DR. OWEN: I would ask our Chairman to put that on the "parking lot" and the reason is straightforward. On the third page of any economic text, if you are trying to forecast you are basing it on a trend and we've got cross-sectional data and that's not a robust way to forecast, but what we're trying to do, we're going to need to forecast.

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MR. CANTOR: Excuse me, Jack. One question. Here where it says Vitamin D, do you mean the tests that are used to guide -- you don't mean Vitamin D, test levels of vitamin D, test for levels of Vitamin D, you mean all the tests which are used to guide vitamin D therapy?

DR. WHEELER: Yeah, yeah.

MR. CANTOR: And so, for example, that might include calcium phosphate, pH, et cetera. And then how did you mix that, for example, like dialysis, what tests? I mean, is there a breakdown as to what tests were included in each one of these categories?

DR. WHEELER: We have a breakdown of that. Do we have that this afternoon in some detail?

DR. HIRTH: We do have that, yes.

MR. AUGUSTINE: We can pull that up for you this afternoon in as some detail.

MR. CANTOR: Okay.

DR. WHEELER: Thanks, Tom.

MR. AUGUSTINE: Let me add one caveat which I am sure will kick off a little firestorm for this

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afternoon. Remember these are just tests that are billed to Medicare, not those tests that are performed. As most of the people in this room are aware, we have this little thing called the fifty/fifty rule and we have all types of lab frequency edits which vary depending on, in many of these tests, from contractor to contractor.

So, there's a lot of variation in what people will bill for. And, for example, if people do not feel that they have enough tests to meet the fifty/fifty rule, they wouldn't bill it at all, because then it may actually show up in the frequency edits to hurt them for future tests that they may bill for. So, there's a lot of caveats to the data. Remember, these is just billed; this is not performed.

DR. WHEELER: This slide shows who among suppliers are receiving or providers are receiving Medicare payments or did receive Medicare payments in the year 2003. And, the principal take-away message here that we'll kind of continue to figure out how to deal with over time is that while facilities receive 98

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percent of the Medicare allowable charges, for this set of services, there's the notable kind of exceptions to that general statement is that independent laboratories, which include laboratories connected with major dialysis firms, receive most of the payments for the laboratory tests.

So, very few of the lab, as we saw a little bit earlier, very few of the lab test payments or allowable charges are actually paid to the dialysis

facilities. And that's, that's going to create a sort of an interesting discussion I think this afternoon.

We did some work on who was ordering the lab tests that we identified as the top 50 or most common fifty lab tests provided to dialysis patients. And, specifically, we looked at the physicians ordering these lab tests. And you can see that most of the tests are ordered by the -- I'll get the term right -- the MCP, which is the capitated physician's -- the capitated payment.

And, so, we took that as really indicative of two things. One is that, you know, most of these

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lab tests are, in fact, ordered by a physician charged with this role but then there are a large number of tests that are ordered by others. And, so, it does beg the question who the others ordering these tests are, and are some of these tests not specifically for dialysis-related services.

Finally, a couple of slides that are going to bear on our discussion about the unit of payment. We're interested in, you know, discussing whether the unit of payment ought to be the individual dialysis service or some measure of time period. And, so, what we have done is to do some analyses looking at patient months as the unit of analysis. And, one bit of information -- and this is a revised slide. There's an error in your printed slide that we caught.

MR. BACHOFER: It will become apparent over time.

DR. WHEELER: The first point is that's nearly three out of ten months, not seven out of ten months, appear to involve an event that interrupted, let's say, a regular scheme of care for a patient. And

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if you can think of a regular scheme of care as having an expected number of dialysis services, that we'll talk about in the next slide. So, about three out of ten months might involve something else that occurred that interrupted standard outpatient dialysis, that leading causes were hospitalization, the actual startup of treatment or patient death or termination of treatment.

This slide gives just a little more detail from the previous one. The dark green bars are indicative of the patient months where we could find no

specific event. And you can see that for those patient months we got 12 to 14 sessions for 79 percent of the patient months whereas under 12 sessions for 20 percent of the patient months. Actually, I'm not sure I'm reading this quite right. Did I get it? Okay. And then with the --

DR. HIRTH: Jack?

DR. WHEELER: Pardon me?

DR. HIRTH: I think 79 percent refers to all patients.

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DR. WHEELER: All, I thought I misspoke.

DR. HIRTH: About 90 percent when you restricted those that didn't have an identified event.

DR. WHEELER: Oh, I thought I misspoke. So let me restate the correct point here. About 79 percent of patient months are 12 to 14 dialysis services per month. And this is for all patients whether there was an event or not, patient months; 20 percent are showing fewer than 12 sessions per month. Okay? And then for patients with an event, which are indicated by the gray bars here, you can see that the number of sessions per month is kind of spread out and sort of all over the place. And once again the leading correlates of fewer than 12 sessions as were the leading sort of causes of, let's say, under leading causes of an event were hospitalization, startup, death, et cetera. There's some others we'll talk about. Paula?

DR. RUBIN: Sorry. Paula?

MS. CUELLAR: I just was wondering, it seems like patient adherence to the prescription is

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missing off of these three correlates.

DR. WHEELER: It is missing and there will be some information about that. What we did just to sort of answer quickly and then defer it to this afternoon, is to identify all of the causes of, let's say, an event, all of the potential events that we could actually identify. And then there's a remainder that you could attribute to patient skipping, lack of adherence or whatever, and that's, we'll have information on how many of those, how many months are characterized by that this afternoon. Thank you.

MR. CANTOR: Jack, what if they went to a different facility or if they were in the hospital, is

that a factor?
DR. WHEELER: That would be another one. We'll have those data for this afternoon as well. So that would be another, depending on how you define a full month of treatment, we also show switching among treatment facilities.
DR. RUBIN: Is this pattern uniformly distributed by facility type, by geography, and, by
0126
location? In other words, it's nice to say that 79 percent had 12 to 14 sessions, you know, if there, you know, in a big facility next door to a hospital, get a patient in and out but it's quite another to say that that same distribution is in a rural place where the hospital is a 50-minute car-ride away and the patient may actually miss three or four for the same sort of illness just because you can't get the patient to and from.
And one of the charges that the Congress gave to this committee as well as to CMS is to be sure and account for things like rural facilities and things like that. And so, as I mentioned in my opening comments, I am concerned that when we look at averages -- and I think other people made the same comment as well -- that there's a lot of noise that gets buried in there depending, or not, depending on some of the kind of the standard characteristics that Nancy and her colleagues look, the way they look at facilities.
DR. WHEELER: Yeah. We have done analyses
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of many measures in terms of how they varied by type of facility, location, et cetera, and some of those we have to show you this afternoon. This one we have not looked at in terms of how it varies by facility type yet.
DR. RUBIN: Right. I knew that because I looked at the slide.
DR. WHEELER: Yeah, so, thanks. Thanks for that. So, that was our sort of quickie-trip.
DR. RUBIN: Maybe somebody on the phone there can press a few buttons and give you the answer in time for this afternoon's presentation.
DR. WHEELER: Phil, are you there? Maybe they're not there. We'll call them, we'll call them at lunch.

VOICES (ON SPEAKER PHONE): Yes, we're here.
DR. RUBIN: Did you give them a lunch break? Oh, there they are.
DR. WHEELER: Okay. We'll give you a call and see if you can do something that Dr. Rubin has
0128
suggested.
VOICE (ON SPEAKER PHONE): Okay. Sure thing.
DR. RUBIN: Great.
MR. AUGUSTINE: Speaking of lunch, we can get to the last, this is the last slide so we're good to go.
DR. WHEELER: That's it.
MR. AUGUSTINE: That's it? All right, everyone. One thing I would like to do is I'm going to having a pad up here and I would like for those of you in the audience who plan on making some comments or ask some questions this afternoon to come up and write your name on here so we will get an idea of how many people would like to speak and so maybe there's, if there's whole a lot we have some extra time may try to provide some more time for public comment. So if you would come up and write your name on here, I'd definitely appreciate it. Other than that, the board en masse will be meeting for lunch. The rest of you, as I said, there are plenty of opportunities and good, nice places
0129
to eat around here. And we will reconvene at 1 o'clock. Thank you.
(Luncheon recess)
DR. RUBIN: Okay. If we could get started for the afternoon session. First I would like to congratulate my fellow committee members for their succinctness in allowing us to be on schedule and, of course, kudos go to my co-chair for actually making it happen. And, so, you set a very high bar and I'm not sure I'll get there particularly since this is the interactive part of the meeting but I'm going to try. What we're going to do now is really go through the next -- you want to hit the next slide button -- and take a look at the various design issues.
The ones that are highlighted are the ones that we're going to talk about briefly, except for case-mix adjustment; we're not really going to spend a

lot of time on that. We want to talk about scope of payment, responsibilities of the facilities and then unit of payment. So, if we could, yeah, go onto the next one, please. So, the critical question of what

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services and/or costs should the expanded bundle pay for, we heard a lot of input from the Committee and I'm going to, well, I guess, do you want me to read these for the record.

COURT REPORTER: Oh, that's up to you.

DR. RUBIN: Well, I'm going to assume that everybody here can read so I'm not going to read each one of them. But basically this is a fairly tall order of what we want to do and what the committee thinks needs to be addressed as part of the bundle. And, so, we really need to keep those in mind when we talk about what those services ought to be. And, if we can go to, there are issues as to broad groups of services that should be in the bundle and that combinations and permutations are illustrated on this slide.

And, simply put, they're including all drugs in all drug-related lab tests, drugs in dialysis-related lab tests, drugs in all laboratory tests as well as all routine services that are related to dialysis with and without including vascular access services. And those need to be defined in a way that,

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number one, is easily understandable to the people who are going to be held accountable for it and, number two, can be easily accounted for. And we heard from the University of Michigan regarding some of the methodologic challenges regarding that piece of it.

So, what we're going to hear for a short period of time and the way the afternoon is going to play out is that there will be a brief introduction for each of these segments. The University of Michigan is going to present some data and then we're going to have some discussion. So, without further ado, Bob, were you going to do this presentation?

MR. WOLF: Yes. I'm going to start out. I'm Bob Wolf from the University of Michigan. And I'm going to go over some of the issues related to scope of payment. And we'll see later on that it's hard to separate the scope of payment which has to do with which services might need to be considered to be bundled in the composite rate from also which suppliers

should be considered.

It's very natural to think of dialysis

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services as provided just by the dialysis facilities but there has been quite a bit of discussion already pointing out that the laboratory tests in particular do involve other kinds of providers. So, in terms of the overall payments for dialysis patients it's important to keep in mind the two different components of the composite rate services which are already bundled together, go over some of the components of that bundle in the next two slides.

And, what we're really focusing upon here for most of the afternoon is different parts of the separately billable items. These are items which are currently separately billed unit by unit and the reimbursement comes for each time that service is provided. And the primary ones we're looking at here are injectable drugs, the laboratory tests and then the catch-all of other, but I think the first two is where almost all of our focus is.

And we will be bringing in the issue of identifying how many of each of these different components are supplied by other suppliers and

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providers other than the dialysis facilities. And one of the questions that we're trying to address here and that we at KECC have spent quite a bit of time on is trying to find the question of what are the related laboratory tests, what are they related to, are they related to regular routine dialysis, are they related to other things that are regularly given to dialysis patients or, as Bill brought up, how wide does the question of delivery of medical care expand here in terms of treatment of the entire health network patient as opposed to just analysis of things through the patient.

There are quite a few drugs that are already bundled into the composite rate. This is a list. I don't know if it's a complete list but it's certainly a list of most of them. And these, in a sense we did not have to deal with because they are already bundled within the composite rate and there are several tests that are already bundled into the composite rate and some of these are specified typically on a per month basis, some on a per session

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basis and some on a per week basis.
And, that's one of the features of I think the intent of the composite rate. It was designed to get the things that are just done almost every single time. So it doesn't vary. It's not discretionary. It's not responsive to the needs of the patient. It's just part of routine dialysis.
The thing about separately billable items and services is they're typically more discretionary, more targeted towards the specific needs of the patient and aren't quite as routinely as are these tests and drugs that put already into the composite rate. So, this slide shows some of the other extra services in addition to the composite rate services which are up at the top line.
Then you can see that in 2003 those represented about $4.2 billion worth of payments, while the next line shows some of the major components that were separately billable services that we're talking about here, including EPO, about 1.8 billion plus, Vitamin B, half a billion, Iron, a third of a billion,
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other injectables down to 76 million.
Then we have a laboratory tests. Now, we'll be talking a little bit about what we mean by this top 50 but it turns out that these do represent the very large fraction of the laboratory tests that are provided by, to dialysis patients, and these come to about a quarter of a billion dollars. And then there's supplies and other services provided by dialysis facilities coming to about 27 million. These are just useful categories to keep in mind. We will be talking about several of these. Paul?
DR. EGGERS: In, earlier there was sort of a, things that the dialysis facility bills for and then other providers, and it isn't clear to me, is this only the dialysis facility billings or does this include the other providers yet?
DR. WOLFE: This does include the other providers.
DR. EGGERS: It does?
DR. WOLFE: It includes claims submitted by facilities, hospitals laboratories and other providers.
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It turns out, well, you have already seen the slide

before that shows that most of the drugs are supplied by the facilities themselves, over 99 percent. Most of the laboratory services are provided by other providers.

So, that's just a major distinction between those two categories of separately billable items and services. When we're talking about the drugs, we're already talking within the framework of services provided by the dialysis facilities. As soon as we get to the lab tests, we have to think very hard about which other providers are included and which lab tests are included in that list.

MR. CANTOR: Bob, under vertical integration of the labs did you account for whether they were part of the same organization of the facilities?

DR. WOLFE: We have not done that here because even some of the chain-related laboratories do provide, my understanding is they provide a fair number of contract services to independent dialysis

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facilities. So, we do know which ones they are. We have them by name but those aren't shown here. They're just shown in aggregate.

MR. AUGUSTINE: And there are ways to connect. That may be something we want to follow up, because the patients are associated with the facility and then you can get the lab tests from the chain labs and maybe tie those together in that way to find out how much of that chain lab's services were provided to that chain's patients.

DR. WOLFE: We have not done that.

MR. CANTOR: Through the patient's name.

MR. AUGUSTINE: Yeah.

DR. WOLFE: And We have it all linked by patient so we're able to attribute all the costs to the patient and aggregate those and come up with cost per session, come up with cost per month and case-mix adjust that to the patient. There is a question then of who would get paid for that patient's services, particularly if that patient's services were provided by more than one dialysis facility and some of them are

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provided by laboratories. Paul?

DR. EGGERS: But that $250 million for the laboratory tests, that includes some amount which may

or may not be dialysis-related?
DR. WOLFE: That's correct. Let me. Let me --
DR. EGGERS: If we were to say that all of that, I mean, suppose all of it was dialysis-related and we said put it in the bundled rate and the dialysis facility will figure out how to pay the labs. Okay? Well, you know, the problem's not insurmountable it seems like to me but if a significant chunk of that is for services which really aren't dialysis-related and they're actually things that, you know, a different doctor, you know, prescribed for something that's, you know, different, then you got a problem.
DR. WOLFE: These are all very good points and we'll be showing some data that are relevant to them. This is just the aggregate number over here.
DR. RUBIN: Mike -- or Nancy.
MS. RAY: I'm sorry. How does this table
0139
relate to the one you showed before the lunch break which was in the data previewed, the 2003 column? Because the numbers don't match. I'm just wondering why --
DR. WOLFE: They're close, however. Which slide are you referring to?
DR. EGGERS: That was a dialysis facility. This is a result.
DR. WOLFE: There was a slide that did not include the other suppliers for laboratory tests.
MS. RAY: Right. I'm looking at slide 34. I guess I would like to see some context of the 3880 for composite rate there and here it's 4176. And even the EPO numbers differ.
DR. RUBIN: Could you repeat the slide number?
MS. RAY: Thirty-four.
DR. WOLFE: One difference is that slide 34 is hemodialysis only.
MS. RAY: Ah, thank you, that's --
DR. WOLFE: And that will generally be true
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through several comparisons. If you try to make several comparisons it will depend upon exactly which patients are included in exactly which facilities. Several of these slides like this one are intended to show the magnitude of these different buckets of

services.
MR. AUGUSTINE: Let me just recommend that that's clearly identified on these slides, so that may be helpful if you can point any descriptive information on the slides it can help keep it straight.
DR. WOLFE: That's a very good point. And we did make compromises in terms of how many footnotes to put on each slide so that you could see the content rather than the details.
MR. AUGUSTINE: Dr. Lazarus?
DR. LAZARUS: I'm having a great difficulty with the term dialysis. There are very few lab tests and very few drugs that are truly dialysis-related. Are we talking about ESRD patient-related? There are very few lab tests that are dialysis-related. I need very few tests for dialysis. I need very few, only

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heparin, for dialysis.
DR. WOLFE: We do have a list of how we categorized. Let me go through several steps and come back to that.
DR. LAZARUS: I'm suggesting that the word dialysis is a bad word for us to be using.
DR. WOLFE: Thank you.
DR. LAZARUS: It confuses and complicates our job. It should be ESRD-related.
DR. WOLFE: Thank you.
MR. AUGUSTINE: And that's a really good point. Even in our unit chart earlier we kind of split out the lab tests by type. There's a type called dialysis which I would assume would be the real dialysis-related test, like KT over V, so when we're talking about the whole group, we may need to kind of change our focus and take a step back.
DR. WOLFE: And certainly there are various ways to categorize those and different people would cut and slice it different ways.
DR. LAZARUS: If we use the wrong language,

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you're going to continue to have the problem.
DR. WOLFE: Thank you.
DR. OWEN: Mike, I'm sorry, you know, maybe I'm the dumb one around the table here. You're making a lexicon issue. Is the issue that dialysis is, dialysis-related is describing a procedure and our focus is a patient in a disease state?

DR. LAZARUS: Well, when you say dialysis to me I'm thinking about a procedure.
DR. OWEN: Okay.
DR. LAZARUS: And I want to know what lab tests and what drugs I need to carry out that procedure. The treatment of anemia has nothing to do with dialysis. It has to do with ESRD. Same with metabolic bone disease, same with all the conditions we're talking about here. So to clarify what we're trying to do, I suggest that we use the proper language.
MR. CANTOR: Bob, I'm y, one more thing. Carrying on from Nancy's comment on the slide 34 it says that were $20 million spent for lab tests in 2003

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but on the slide 50 it says there are 249 million. That's not simply due to the difference between hemo and all dialysis?
DR. WOLFE: No. That's due primarily to the fact that slide 34 was just those labs provided by the facilities themselves.
MR. CANTOR: Oh, I see, whereas the others separate billable or --
DR. WOLFE: And this includes a separately billable here, that's right.
MR. BACHOFER: And also from, slide 34 is just looking at claims submitted on the first slide, just claims submitted by dialysis facilities. It does not include claims submitted by --
MR. CANTOR: Other providers.
MR. BACHOFER: -- other entities.
MR. AUGUSTINE: All right. Calm down, everyone. Let me just make a comment, that for those in the audience who are having a hard time hearing this, if the board could be helpful and speak as well as we can to the mike so they can hear clearly in the

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audience, I would definitely appreciate it.
DR. WOLFE: So we have just resolved two differences between slide 34 from this morning in your handout and this slide. One is slide 34 in the morning was hemodialysis only and the other difference is, well, this current slide includes all patients, and the other major difference is in terms of which laboratory providers are included. The one from this morning included only the labs provided by the dialysis

facilities. Here we're going to be addressing the question of other types of providers and the other providers are included here, the independent labs and the labs associated with chains.

So here we have a list of the other injectable drugs. So far in most of our slides we focused just upon the top three, EPO, Vitamin D, Iron. We've expanded the list further down and you can see the reason that we stopped with Iron; that's a 342 million. The next biggest category is down in the twenty millions, and you can see it drops off fairly rapidly beyond that although when you put them all

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together the other category here is still 7 million. But by focusing I will see big three, EPO, Vitamin D and Iron, I think that that is a useful way to do it in order to assure that we understand what's going on with those and then how far one moves down the list or whether one just includes the whole list is part of the charge of this committee, I believe, is to give recommendations and suggestions on how to address that question.

DR. RUBIN: Right.

DR. WOLFE: So the dollars here do include the patient component of the reimbursement here. And these are only injectable drugs that are included on this list. For dialysis-related lab tests, we have not only the question of which lab tests to include in the list but which providers. And, we have also brought in the extra information of who ordered those lab tests. We think that that may be a criteria to help you think about which labs may be more ESRD-related and which may be other kinds of disease-related.

So here's what we did to help cut through

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what we think is a fairly complicated set of information. We have information provided by facilities. We have information provided by the other providers, the other laboratories. And the question in front us was how do we identify ESRD laboratory services. What we did was we went to the top ten laboratory providers, that is, we looked at just the identifiers of the providers and classified all of the lab tests and put them in buckets according to who was providing it and looked at the ten biggest buckets. And we chose that because that's about 85 percent of

all of the lab services provided.
So, it's a large component. And our thinking was those would be laboratories that were oriented primarily towards dialysis patients, that there would be a lot of collapsing of services into a few providers here. And then what we did amongst those providers, those top ten providers, was we looked at the top 50 types of laboratories that they did in terms of dollars. We also did it in terms of frequency. There are fairly similar types of ranking there.

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Again, our objective was to try and identify the bulk of the lab services that are being provided and understand them. There are many hundreds of other lab services provided but they may be, well, they clearly are much less frequent, much less important and much less consistently provided. So these top 50 lab services, the drawing the line at fifty is somewhat arbitrary but we're capturing over 98 percent all the lab services provided by these providers by looking at the top 50.

Then we went back with that list of particular types of labs and looked at all providers, no longer limiting it to just the top ten but whoever provided those services. And the logic was by getting the top ten we're getting dialysis providers. By looking at the top 50 we're getting those things that are regularly given to ESRD patients. And then we looked to see who all the providers were, not just the top ten.

MR. CANTOR: Bob, this is all done by dollars, not numbers of tests?

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DR. WOLFE: That's right. Although there's a fairly good consistency between those two orderings of different types of services but it's not perfect.

MR. CANTOR: But some of them are much more expensive than others.

DR. WOLFE: You're absolutely right. You're right. Then in addition we did categorize these into clinical groupings which may or may not be useful and we saw some of those this morning. This summarizes who provides these different labs tests in very broad categories. The top line is just all other nondialysis facility providers, including those that are associated with chains. And that's 87 percent of all of these

different dollar services provided, 218 million.
Then amongst the institutional providers -- that's the dialysis facilities -- we have them categorized here according to type of dialysis facility. The big one is in the second line. It has a number 72 in front of it. That first column of numbers is very meaningful to us. It identifies a type of bill.

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The word labels after that may be more meaningful to most of you and the second line there is the independent renal dialysis facilities. Above there is the hospital outpatient facilities. And you can see that those two along with other hospital-based facilities do most of the lab tests within dialysis facility providers. And again most laboratory tests here are provided by nondialysis facilities as shown in the top line.

MR. AUGUSTINE: I want to make sure that point is clear because the line, I guess number 13, are those tests are done within the facility, and, most of which is in the very top line, the freestanding, are those tests that are performed within but sent to an independent lab that's affiliated with the chain or the large dialysis organizations. So, I just want to make that point clear.

MR. CANTOR: It just has to do with where the test is run.

MR. AUGUSTINE: Yes.

DR. WOLFE: Yes.

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DR. HIRTH: And to amplify that a little bit, in the top line the freestanding laboratory providers, the eight providers that we have identified based on name as being dialysis chain-related account for about 85 percent of that 218 million. So, those chain-related laboratory providers are really the bulk of that freestanding. In terms of the institutional, it's a little bit less clear because the only ones that are clearly coming from the dialysis unit itself are the type 72 claims.

The others, for example, the hospital outpatient, it could be a hospital outpatient lab that has a hospital-based dialysis facility that's sending its labs through that hospital's own outpatient lab. It could also be that the patient went for some other

unrelated type of medical care and had a lab test for a similar code, one of our top 50 codes billed by the hospital outpatient lab but it isn't necessarily coming from the dialysis unit.

DR. LAZARUS: How did you handle the fifty/fifty rule on this? I'm still not clear. If the

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facility, the doctor orders a lab test in a facility, the facility sends it to the local hospital, either outpatient or inpatient and has it done, if it's in the fifty/fifty rule or not in the fifty/fifty rule, how is it managed here?

DR. WOLFE: All we're capturing here are paid claims. So, to the extent that you have lab services that don't get reimbursed because they are reimbursed under the composite rate, they're not included here because we don't even see them. There's no way we can find them.

DR. LAZARUS: But the hospital bills and then they, these are hospital bills to Medicare?

DR. EGGERS: It's a hospital facility. It's not a hospital bill.

DR. LAZARUS: A hospital facility but --

DR. EGGERS: That's just the organizational unit, not the type of services.

DR. WOLFE: So I think that most of our focus here will be on the top line, which is the independent laboratory providers and the 72 line, which

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are the renal dialysis facilities, some of whom are performing their own separately billable lab services and billing for it. The others, as Richard has said, are more ambiguous because it's not really clear. While they are provided to dialysis patients, it's not clear that it was provided that it was ordered in any way through the associated dialysis facility within that unit.

MR. AUGUSTINE: Nancy, you had a question?

MS. RAY: So, for the type of service 13, you didn't look at whether or not there's differences in the types of tests run through, whether the type of services is a 13 versus whether it's a 72?

DR. WOLFE: They are limited to the top 50. So these are tests which are routinely given to ESRD patients and they are amongst the most common tests given to ESRD patients but they might have been ordered

by a different doctor for a different reason and still have the same code. We can't tell. At least we have not broken down here who ordered these tests. We can do so for the top line. We cannot do this so for the

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institutional providers. For those of type 72, they're clearly dialysis facilities. I think almost everybody would agree that everything there probably should be considered. It's a little bit more ambiguous for some of these other lines.

MS. RAY: Right. But we just don't know the extent to which in a given hospital when they do their labs that for whatever reason they're not coding it as a 72, they're coding it as a 13. I mean, I don't have any information about that one way or the other.

DR. WOLFE: We don't know. That's right.

MS. RAY: But those tests account for, I mean, putting aside the freestanding, those in the 72 account for the rest of all the tests?

DR. WOLFE: That's right.

MS. RAY: Yeah.

DR. WOLFE: Yeah, and we're showing these slides not -- to show problems as well as solutions. These are the facts that we have in front of us and this is what we have to deal with and there is some ambiguity.

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We do have a list of the top 50 that were included here. Here we just show the top ten so that you can get an idea for what's on the list. So this is, amongst the most frequently provided laboratory tests, these are the ten most common in terms of dollars. And you can see it's very close to frequency as well. And I think I'll just let you read them rather than me mispronouncing some of them. Okay. Are there any surprises there?

DR. LAZARUS: Aluminum is awfully high.

DR. WOLFE: Aluminum is high? Okay.

DR. OWEN: Hemoglobin A1Cs are low.

DR. RUBIN: I think that that's kind of a good segue into -- Bob, if you could just throw up the next slide -- into the discussion part of this. And, we have a fair amount of time for discussion of the data. The issue, Bill, that you raised about the hemoglobin A1Cs being low I think highlights who is ordering it and where --

DR. OWEN: Right.
DR. RUBIN: -- not whether or not the
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patient got one. And one would hope that that frequency is not indicative of what the patient is getting.
DR. OWEN: Although that's data from USRDS, there is some data that we have from New Jersey dataset that suggests that they just aren't being done.
DR. RUBIN: It's possible but I think to maybe put some framework around what I would like to see the group do this afternoon, and this in particular, we've gotten an overview of the data. Now we need to ask, number one, what's the quality of the information that we got and what can we do to improve it to better inform the construction of the bundle; secondly, what data haven't we seen that we need to help us and form the construction of the bundle, and then is it reasonable to expect that we can get that information in a timely fashion.
And, that's why we have these folks here to answer those questions. And, then if we're looking into what things ought to be in the bundle in terms of the scope, what criteria should we use to either limit
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the expansion or increase the expansion. So, the floor is open to the committee.
MR. AUGUSTINE: Help me understand something. I want to go back to the hemoglobin A1C comment. I don't want to spend too much time on it but I want to understand. It says 400,000 of these tests were done on the top ten lab test slide.
DR. RUBIN: Right.
MR. AUGUSTINE: And we have about 300,000 patients. You would expect them those to be done quarterly, correct?
DR. OWEN: Not hemoglobin. Hemoglobin A1C is not bundled. You guys have it characterized as glycated hemoglobin. I just want to clarify that.
MR. AUGUSTINE: Those are different tests.
MR. BACHOFER: Okay.
MR. AUGUSTINE: And so you would expect to see a lot more if proper management is done and the question I had was -- and Linda and I were talking about it -- is that if it was done in a PCP's office, this should still show up in here.

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DR. LAZARUS: No, no. Some nephrologists do not and refuse to manage diabetes, largely done by PCPs.
MR. AUGUSTINE: But see if they did it would be, it would show up in these numbers. So, in other words, a lot of these patients aren't getting evidence-based care.
DR. OWEN: That's what I wanted to pursue with these guys in terms of testing like that. If the hemoglobin A1C was done by the primary care physician and he, she has a UPIN number, I'm assuming you guys, whether they're nephrologists or not you guys are going to capture that it was done, that the test was done.
DR. WOLFE: Yes.
DR. OWEN: So I return to my statement. It's not a suggestion of where it's being done, it's a suggestion it's not being done and goes to the bigger question that I raised earlier that several people have raised here. What are we going to be addressing to pay for? Are we going to address ESRD alone or are we going to address the management of major comorbid
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conditions associated with it?
DR. BURKART: Just for clarification, I agree with all the statements that were just made but if the PCP ordered it at the facility and it was drawn at the facility, it should be showing up here. If the PCP ordered it in their office and they went to some lab that is not related to the dialysis unit --
DR. EGGERS: It would still show up here.
DR. BURKART: -- would it still show up here?
DR. EGGERS: It would still show up here. This is the universe of laboratory tests in the ESRD database, billed to Medicare for these patients.
MR. AUGUSTINE: Independent labs, ESRD beneficiary.
MS. RAY: Wait. I thought the labs that were showing up here were the laboratories associated with --
DR. EGGERS: No.
MS. RAY: No?
DR. EGGERS: Most of them are. 85 percent
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of it is.

DR. WOLFE: Then let me identify -- let me go through the step again.

DR. RUBIN: Well, just one second. Okay. I think that for this to make sense to somebody that's going to be looking at it in the future, why don't we let people finish their sentences rather than kind of think of what we think they're going to say and answer that question. It probably would be better for everybody concerned. So, I'm sorry to interrupt.

DR. WOLFE: We first identified the large institutional providers of the laboratories because those would be oriented towards dialysis patients. Then we looked at the top labs that they provided but then we went back and looked at all providers of those services, including physicians, including other laboratories. So, they're included in there but they represent a very, I shouldn't say a very small but less than 15 percent of the provision of those services. I can say that with certainty and I would suspect it's much lower than that.

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MR. CANTOR: It is the right incidence, if there's 100 or 150,000 diabetics, four times a year is about this number.

DR. RUBIN: Well, I think it would be closer to 600,000 than 400; 150 times four is 600.

MR. AUGUSTINE: Well, the reason I'm, you know, I'm not, up to 60 percent are diabetics if I remember correctly.

DR. WISH: No, no, 45.

MR. AUGUSTINE: 45?

DR. RUBIN: Anyway, I think that regardless of this particular test and this particular number, I think Dr. Owen raises a critical question and that is are we talking about managing, are we talking about including things that you need to manage the entire patient in the bundle or are we talking about putting things that are only related however we define them to treating the fact that this patient doesn't have appropriate kidney function in the bundle.

And I think that that's really a fundamental question. I think clearly this is where

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the issue of the bundle gets a little murky as it relates to a whole host of both drugs as well as lab tests. And it's something that merits some discussion.

I gather that Dr. Owen would favor putting things that take care of the entire patient in the bundle as several other people had talked about in their opening statements. Dr. Lazarus?

DR. LAZARUS: It's essential that you align a nephrologist if we're going to do that. Without a physician that's willing to who manage that, you cannot include this in. So, unless the MCP is going to say to nephrologists, you will manage the diabetic care of the patient on ESRD, there's no point in the world us talking about the providers doing this.

MR. AUGUSTINE: Well, let me, and this kind of goes back to your comment earlier about the dialysis-related versus ESRD-related. But to address your point, I think we have been open all along and we've had a long two years with the MCP chains and from day one, one of the things that we talked about with the, with RPAs and the community at large was that we

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were interested in moving toward aligning incentives between dialysis facilities and practitioners and are still interested in doing so and I do know there's increasing discussions about how we can do that.

DR. LAZARUS: Who in this panel speaks for that, is that John or is that Jay; who speaks for the nephrologist here?

MR. AUGUSTINE: Well, we don't have a quote-unquote nephrologist representative because that wasn't one of the specific groups of people that were listed in the legislation but we do have some people with expertise, Jay, John, Bill, and we have a lot of nephrologists on this panel that can add some input. But there aren't official representatives of RPA raised. Is that a fair characterization?

DR. OWEN: I think it's a very fair characterization. I mean, as you know, Mike, going back to your tenure with the RPA there has been substantial debate about the role of the nephrologist as a disease management caregiver, and, I think it's fair to say that it may still exist because there is a

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schism in terms of what is compensated for versus what some but not all nephrologists desire. And, you know, the extremes, either I am the dialysis jockey or I am the doctor.

DR. LAZARUS: Well, can we proceed without

knowing?
MR. AUGUSTINE: Well, that's not what, I mean, we can make recommendations but I don't believe, you know, requiring that physicians incentives be aligned or within the scope of what Congress has charged us to do.
DR. LAZARUS: Well, then how am I going to determine what's in the scope here if it largely depends upon my partner or in managing it. I don't want to put a hemoglobin A1C in if there's nobody to manage that.
MR. AUGUSTINE: I'll speak, the relationship between the facility and the nephrologist from my understanding, and I'm not a practitioner so, I'll leave it to others to verify my comment is not as tenuous as some may make it out to be. I mean, in the

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new conditions for coverage we actually try to strengthen the relationship between practitioners and dialysis facilities at least with the medical directors and each facility has medical director agreements that should specify what our expectations are of the medical director and they do have credentialing for those people that practice in those facilities.
DR. LAZARUS: But none of those things relate to the practice of medicine, Brady. None of them relate to the practice.
MR. AUGUSTINE: Some facilities do, some facilities do have relationships, do have in the MBA agreement requirements that you meet certain quality outcome markers or certain process markers in order to receive full or partial payment. And my understanding, those relationships are growing but they, but an off-topic that needs to be dealt with as well is the discussion with, the disagreement between RPA and the Department of Health and Human Services that is currently underway.
DR. RUBIN: Dr. Owen?

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DR. OWEN: Mike, rather than asking what the doctors and/or their societies want, we do have a representative here from the patients. Wouldn't that be the person to ask what they want since they're the recipient of the care?
DR. LAZARUS: I'm not sure that they're going to make the doctors do as they want either.

DR. OWEN: Well, I know when I navigate the health care system I have very strong desires as a patient, as a consumer and they're, the consumer and at some level the payer, even the ones who aren't patients, they're potential payers. So maybe I'm being a little unfair by saying, you know, Chris, I would be interested to hear, would you in your experience as a consumer, would you as the executive director of your society and lastly your membership has said about when the patient is in the dialysis unit who they want to be their doctor.

That's what we're talking about. Am I going to have one doctor who is a nephrologist in the dialysis unit or am I going to have to bounce around

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from place to place? And since one of the great disparities in health care is driven by an absence of an ability to navigate the system, Bill Owen's bias is it should be the nephrologist sitting there.

MS. ROBINSON: I'm more than happy to respond to you. I will tell you that it goes both ways in that there are patients who do want the nephrologists to take complete control of their health care and not have to rely on other physicians but there are also patients who want to see specialists and that if they do have diabetes, they still want to see their physician who can treat the other aspects of their diabetes besides the ESRD.

So, I think, you know, it's something we really do need to look at as we move forward with the bundling. As a patient it would be very nice to see the bundling incorporate everything but you're going down quite a line. Then will we be incorporating mammograms? Will we be incorporating all sort of other things into the bundling if we're getting outside of the ESRD? So, I would be hesitant in that regard.

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MR. AUGUSTINE: Let me, if I can, Mike, let me see if I can rephrase your question. I think one of the things Mike was asking about -- and correct me if I misstate it -- is that he was concerned about moving forward with an expanded bundle and potential pay-for-performance for facilities. Would that of itself have value even if the practitioners did not have some type of same arrangement, is that correct?

DR. LAZARUS: Well, I guess that's one way

to say it, yes.
MR. AUGUSTINE: And what would your comment be on that? If the facility had an expanded bundle and pay-for-performance and quality and yet practitioners are still getting paid by the MCP as it currently exists today, would it still be of value to you as a patient?
MS. ROBINSON: Of course it would be of value. There would be better outcomes for the patients.
DR. RUBIN: Well, I think -- well, I'm going to let Dr. Lazarus speak for himself. He's
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pretty good at that.
DR. LAZARUS: Well, the problem is that I've agreed to the bundle and I've agreed that I'm going to do certain things and reach certain goals. If my partner says thank you very much, I'm not interested in that, I've got a fee for service, it doesn't make any difference to me whether you meet your goal or whether you need your bundle, you're on your own. That system is not going to work for your bundle.
MR. AUGUSTINE: I think that's one of the reasons why at least at the facility level why it was pointed out, it's very important that these activities occur at the facility level as opposed to having some differences in practice patterns within the facility because some providers are in and some practitioners are in and some are not. So, it's very clear that we need to be facility-based, at least facility-based.
DR. RUBIN: Dr. Burkart?
DR. BURKART: The patient says I know I got my arm stuck out here and the blood's circulating and I know my endocrinologist wants a test, can we drop why
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I'm on dialysis? So, I agree with is it part of the bundle payment but who's responsible is another thing. Sometimes it's just drawn at the dialysis unit for practical reasons, not necessarily, you know, because the nephrologist is going to react to the test also.
DR. RUBIN: Absolutely. And I think that there is a fundamental question that maybe we should "park" and then move on, but, and hopefully we can get some consensus on this. If for whatever reason we want to hold some unit of analysis -- in this case a facility -- responsible for a whole series of good

medical practices, like influenza immunization, pneumococcal immunization -- if Kris wants mammography, we can throw that in, whatever -- that's very different than holding physicians, the physicians that may practice there with the possible exception of the medical director who can actually order those things, responsible for acting on the results of those things. And, I think we need to be very careful about separating that.

So that if it's a quality measure, we need

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to say that every patient that is diabetic, we need to draw a hemoglobin A1C quarterly, that's a pretty easy thing to specify, put in a bundle, and we need to figure out what we're going to do with the result of that. But, it's -- and now I'll editorialize and say I totally agree with Dr. Lazarus that if Nephrologist A doesn't want to manage diabetes, you can throw in those results from now until he's green and it's not going to do anybody any good.

So, you know, I think that may be the next step, and, again, I just want to caution this group, this demo is not going to solve the healthcare delivery problems of the country of which is this is a microcosm. So, we ought to try to figure out what it is we want put in here, who we're going to hold accountable and then make sure that they have both the authority and the responsibility to do that. Jay.

DR. WISH: I just want to make one comment and remind everybody of the fundament misalignment between bundling and best practices. And I was just looking at aluminum and I think a number of us were

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surprised to see aluminum so high. And what I was going to say, if you want to get rid of aluminum as a common practice, put it in the bundle and don't require it.

MR. AUGUSTINE: Let me point out, let me point out that there are various, I mean, I think it was aptly pointed out this morning some of the caveats and characteristics of a fee for service as opposed to a capitated payment system. You know, we are quite aware that there's potential underutilization. I think one of the things I do want to bring into the discussion are that we have discussed the use of guards in the conditions for coverage proposed rule against

underutilization. For example, it states in there that patients will have hemoglobin till 11 (phonetic) or corrective action plan in place or some type of documentation as to why they can't meet the KDOQI standards.

As well there's discussion and some, we elicit some comment on use of other types of minimum standards. And so the idea is we need to guard against

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underutilization. That's one means to do so. Of course pay-for-performance is a major activity currently in development and of interest to the administrator of CMS. And there's not only within different provider types but also there's all types of physician activity with regard to pay-for-performance as well. So, to say that one will go forward and the other is not of interest I think is going down the wrong path. I think we're interested in both and align them as well. Paul?

DR. EGGERS: It appears to me that we've kind of gotten to the point right away where we're talking about things on the margin and we haven't sort of agreed in principle on things. I would hope if there's going to be a bundle at all, that we could kind of agree should be in there and in fact gobbles up most of the dollars, and, you know, taking the Willy Sutton approach to economics, which is to go where the money is.

You know, if we go back to the Table 34, for example, and, you know, just look at things that

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are billed by the facility, if we start off there do we have agreement that things that are billed by the facility are pretty much open to include it in, before we start worrying about outside providers, is that, these things are okay to be thinking about? Because if we're not, if we're going to say, well, EPO, you know, isn't the thing we should put in the bundle, then, you know, we can close up shop and go home, right?

So, you know, there's no bundle at all. But, once we put EPO in there, I mean, I calculated that we got 65 percent of all the dollars, extra dollars beyond the composite rate taken care of, okay? And if you put Iron in there, that's another 12 percent or Vitamin D is another 18. You get 95 percent if you just do those three.

If you do those three alone and say that's all we're going to do is, you know, going to put all those in, you got 95 percent of the dollars outside of a composite rate that we've been talking about today. And that's so, I'd just as soon not spend hours and hours worrying about how we're going to, you know, make

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that extra five -- maybe deal with that and all that kind of stuff but can we start off by going where the money is.

MR. CANTON: And that's fine, Paul for the drugs but when you get into the lab categories, you have the same lab --

DR. EGGERS: Yeah, but I'd just as soon wait in the lab categories. Let's get some direction here on the things that are easy. Can we do easy things before we go to hard things?

MR. AUGUSTINE: That's a good point.

DR. EGGERS: Or are they easy? I mean, is somebody around the table going to tell me, that, you know, EPO is, you know, you can't put EPO in a thing in there because it varies by patient and, you know, we'll be tying people's hands. I mean, if, you know, that's going to be a decision, then, as I say, we're not going to go very far.

DR. RUBIN: Well, you raise an excellent point and one could certainly construct this the way you suggest. We're actually kind of constructing it a

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little differently in the sense that, to use your example, we may decide that EPO should be in and then we're trying to figure out how to make it a fair payment through whatever it is that you need to do, if, in fact, you need to do anything, so that the facilities are well-served, patients are well-served, et cetera.

DR. EGGERS: Well, let me --

DR. RUBIN: I don't think, I don't think that there would be any broad disagreement that the things you mentioned ought to be in a bundle with the caveats that they need to be appropriately accounted for with all of the qualifiers that were brought out in the members' discussions earlier on this morning. So, we can go do that. I was trying to look at this a little differently and I agree with you that it is on the margin but if you believe all the data, the margins

are so small, that maybe whether it's in or out might make a difference in who comes to play, number one.

And number two, I think that Bill Owen raised a fundamental question, which I don't think is

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marginal, regarding what we're trying to accomplish here. And, I haven't heard any clear-cut consensus as to whether he's on the right track or the wrong track in that regard although we're moving there. So, if we could, in the next few minutes, and we'll come back to your question, because, that's kind of when we have heard all of the information. Is there any more information that we would like to ask our contractors for as it relates to what might be in and what might be out? Paul?

DR. EGGERS: I think a percent of patients who get -- and I don't know how to quite calculate this right off the top of my head -- who actually receive one or each one of these services, what percent of patients get EPO, what percent of patients get Iron, what percent of patients get Vitamin D and so on and so forth down the line.

I think that helps in terms. My feeling is that if a hundred percent of patients get EPO, you know, you can maybe risk adjust or something but that makes a strong case that if you get something, you

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know, in fact, many of these are that way, where, say, 20 percent of the patients get something, then we start thinking about, well, do you want to put it into a system that goes to 100 percent of the patients and let the facility decide on that -- maybe that's not it, I don't know -- or, you know, is there a case-mix thing that you really need in order to determine who gets that particular sort of thing.

DR. RUBIN: Right.

DR. EGGERS: But I find that, that just helps put in context for me, are these dollars just small dollars that are going to a hundred percent of the patients or is it a small possible number of patients that are getting this in particular? It's just helps me but that's a data thing.

DR. RUBIN: And I think that's something that's pretty easy for us to do. Mike?

DR. LAZARUS: I would like to see the full list of labs and the full list of drugs and a split as

to whether they were ordered in the facility or outside of the facility.

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DR. RUBIN: Okay.

DR. HIRTH: Yeah, to address the first question very briefly, we have some information with us on the distribution of expenditures for various items across patients by percentile so I can't explicitly answer what percent did or didn't receive but for EPO it's zero dollars at the 5th percentile but there's positive spending at the 10th percentile so more than 90 percent received EPO. That's across all modalities. Vitamin D is zero dollars spending at the 25th percentile, positive spending at the 50th percentile, so somewhere between 50 and 75 percent received Vitamin D. For Iron it is also zero at the 25th and positive at the 50th. So for these three it's a majority in all cases.

DR. WISH: Can I just answer? You probably know from the CPMs, which is the random sample of hemodialysis patients.

DR. EGGERS: I've heard of it.

DR. WISH: Right, that the 95 percent of hemodialysis patients get EPO and about 69 percent get

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IV Iron.

MR. AUGUSTINE: Something that I think would be helpful is like on slide 34, where it breaks out the major components, if we could see that by what's billed by the facility and what's not billed, you know, billed outside the facility.

DR. HIRTH: Actually, we have that in a later slide.

DR. RUBIN: Yes.

DR. EGGERS: Again the first principles here, sometimes we talk about hemodialysis patients and sometimes we talk about hemo and peritoneal and home patients, I presume. Do we have agreement about the bundle of services, what types of dialysis, does it cover all types of dialysis, is that what we're looking for? I don't know, I mean.

MR. AUGUSTINE: Well, that's something we need to talk about.

DR. EGGERS: Okay.

MR. AUGUSTINE: I mean, if we want to, you know, encourage flexibility and not, you know, have

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payment policy dictate what type, you know, affect practice patterns and allow practitioners and patients to determine what's best for them, then I wouldn't recommend going, you know, farther away than what, kind of the way the system is set up right now, where they're paid equivalently, except for separately billables.

That will also get us back to where we started, and one of the reasons we paid PD the same as hemodialysis as far as the composite rate was concerned, is that it would encourage and I think the Department and Congress and CMS have all made very public statements that we would like to encourage the use of home therapies and I think we all know that has not occurred and part of the reason for that is the increasing use of separately billables, which are more, much more advantageous and accessible in-center than they are for home patients.

So it would be, if we kind of expand the bundle it would right the ship, so to speak, and put us back to where we started as far as for those patients

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for which it was clinically appropriate PD may not only may be better clinically but also better financially for the provider as well.

DR. EGGERS: I concur. That's what I would like to see, is the most inclusive. I just wanted to see if there's anybody that disagreed.

MR. AUGUSTINE: Okay. Anyone have any other comments; is there any disagreement on that, or -- okay.

DR. RUBIN: Okay. Why don't we move on then. I think we're up to -- here we go, our next slide. So, what we want to talk about in this that I think is kind of the part of the program where we get -- and for those of you that have these we're on slide 59. This is where we can expand the discussion and to help answer the question that Dr. Owen raised about services and that we would like to see included at the facility level.

And, clearly these are services that would be under the plan of care, services that are ordered by -- the term of art that's being used here is MCP

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practitioner but the one that actually gets paid for

taking care of the dialysis patient. And, we could also add to that a list of services by "Hicks-Picks" codes if necessary which from this morning's discussion may well be if we decide to do some vascular access stuff.

And, we can, obviously you can do the opt-in or opt-out methodology which here is called inclusive and exclusive, and then are there are some technical issues as to how you would bill for it and therefore account for it. So, there are a lot of ways to slice and dice this in terms of the data. One is to look at the services -- next slide. Next, one is to look at the services that are provided directly to dialysis patients by the ESRD facility and then services provided by everybody else and everyplace else.

The others are sources of lab tests that might be related to ESRD, related to the use or nonuse of injectable drugs or other lab tests that deal with the welfare of the patient or in some cases the

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potential risks to the healthcare workers at the facility. And, then I think at some point we're going to have to deal with those patients, while small in number but may make a big difference are those people that get service at multiple facilities during some unit, some time units, unit of analysis. So, why don't you --

MS. RAY: Can I ask a question? Can I ask a question?

MR. RUBIN: Yes.

MS. RAY: Going back to the --

MR. AUGUSTINE: I'm sorry. Could you speak to the microphone?

MS. RAY: Sorry. The top ten lab tests and the pertinent data combined, it would be helpful, I guess, because I'm not a physician, I get to have some sort of synthesis of, for example, the issue was raised that the hemoglobin A1C, we would have expected in the ideal world to see more of these, to have some sort of synthesis of are there evidence-based guidelines after that suggesting that particular tests are either

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appropriately being ordered or overused or underused among this list or anything outside of this list?

DR. RUBIN: I think that's a great comment.

And if it doesn't come up during the course of the discussion, let me just presage it by saying what would be on that list will be to a very large degree a function of what you believe the answer to what we're trying to do here is whether it's taking care of the entire patient or just taking care of trying to right the wrongs of somebody that doesn't have functioning kidneys.

For example, there are a whole bunch of things that the U.S. Preventive Health Task Force has recommended as routine tests that adults should have, not the least of which is cholesterol screening. That's not in here. I'm not advocating one way or the other but there are -- and this is an area where there are guidelines, there are published recommendations, et cetera.

And, oh, by the way, if you actually followed the results of that test, depending on whether

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you believe Eric Topel of the Cleveland Clinic or other recent writers in the New England Journal, that would add somewhere between 16 to $24 billion a year to U.S. healthcare costs, which, you know, gets interesting here in things like that. But, I think the point is that they're well-defined guidelines that in the draft conditions of coverage CMS suggests they're going to incorporate by reference and we could certainly add those tests and get some dollar value. Oh, are we running out of time again.

MS. KELLY: No, not till 2:30.

DR. RUBIN: Okay. Jay?

DR. WISH: I was just going to answer Nancy in terms a number of these tests that I think everybody would agree are ESRD-related. There are DOQI guidelines that do specify frequency.

MS. RAY: And that's what I was going after more, because one or two people commented on the aluminum test and that just started the thought of, well, to what extent are there certain tests here that are either being underused, overused, appropriately

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used. I mean, in the aggregate these tests account for a significant amount of payments, about $250 million, I think, which is what you had --

DR. RUBIN: Right. Exactly.

MR. AUGUSTINE: And I'll let the clinicians

follow but to my understanding, the only thing that has been recommended clinically is to avoid aluminum-based binders, if that's correct, so that's why I think we're so surprised to see so many aluminums in there.

DR. WISH: That's correct. The Dabone guidelines do not recommend routine screening for aluminum levels. They do recommend quarterly parathyroid hormone levels for patients on Vitamin D analogs. AMA guidelines recommend quarterly Thuratin (phonetic) and TSAT testing and the CDC recommends yearly hepatitis B service, actually monthly hepatitis B service antibody.

DR. RUBIN: It depends on your status.

DR. WISH: I'm sorry. Yeah, depending on your status but yearly antibody and monthly antigen, depending on your status.

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DR. LAZARUS: But that doesn't have anything to do with aluminum consumption, that has to do with purity of water. I mean, you can drop -- this happened in one dialysis unit in Spencer recently -- a wrench into the "dialysi," which contaminated ten or twelve patients. If you don't monitor, you don't pick it up. The question is the frequency but not that it should be done.

MR. AUGUSTINE: Exactly.

MR. CANTOR: There's evidence in here as Jay pointed out of perhaps low numbers because, as you said, Jay, parathormone is recommended by KDOQI quarterly but if there's a change of Vitamin D, it's monthly and the frequency here 3.6 times per year so there may just be just in general lower numbers than expected.

DR. RUBIN: Okay. Were you going to take this part, Richard?

DR. HIRTH: Yeah. Okay. Very conveniently this is the slide that was asked for a few minutes ago, that splits some of the payments between what goes to

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the dialysis facility and what goes to everybody else and kind of confirms what have mentioned earlier today, that in a sense drugs are easy and labs are hard. Dialysis service itself obviously is coming from a dialysis facility. The drugs and biologics are almost exclusively coming from the dialysis facility. It is really relative to 1.8 billion in EPO, it's a very

trivial amount from that that's coming from other providers, less than a million dollars.

No discernible Vitamin D coming from elsewhere, a small amount of Iron, about a half a percent of the total Iron billings. For those other 11 next most prescribed injectables or next most costly injectables coming from dialysis facility claims. When we look for those same 11 injectables in other facilities, we do find that about 5 percent of the total is coming from elsewhere.

Again, a vast majority is coming from the dialysis unit. With laboratories you get almost the flip side of that. A relatively small amount of lab tests are actually being billed for on the type 72

bills, in other words, on the dialysis bills themselves, and the vast majority is coming either from freestanding labs.

As you saw earlier, that makes up about 218 million of the 236 that's coming from other providers. About 85 percent of that 218 million from freestanding labs is coming from labs that based on our perusal of their names we have identified as chain-related labs and about 15 percent from others. The remaining 18 million was what we have seen from, say, hospital bills and other types of institutional providers.

In terms of the supplies and other services, that's one category here that's somewhat unique in this table in that we only looked for those on the dialysis claims. In other words, that $26.6 million is just everything that was paid for on a dialysis facility claim that wasn't composite rate services, wasn't drugs and biologics and wasn't lab tests.

We haven't kind of constructed a list of codes that appear as a bit of a grab bag in some, you

know, a fairly long list of things that it's fairly uncommon and there aren't a lot of dollars in so we haven't constructed that list and then gone to the other types of claims in the Medicare database to see how commonly those things were used elsewhere. Okay. Questions on that before I move on?

MS. RAY: So that the other includes claims submitted by physicians when you are looking at the injectable drugs?

DR. HIRTH: Yes. In terms of the only thing that does not include claims from anyplace in the universe of the Medicare database is the supplies and other services, that final category. That's 26.6 million. Everything else, the drugs and the labs, we looked for those same codes regardless of where they were billed.

MS. RAY: Again just some clarification. So, for the other injectables that's the other injectables, other ESRD injectables?

DR. HIRTH: Right.

MS. RAY: Not all other injectables that

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may be administered by oncologists or --

DR. HIRTH: It's the 11, that we described them. Among the things that were billed, injectables that were billed for by dialysis units, the big three are the separately identified and the other are the next 11 most expensive among things that are billed for by dialysis units.

So generally, you know, oncology drugs and the like would not have made that cut. And we have that list if anybody is interested. I think we had it on an earlier slide as to what the specific agents are. Okay. Then the question of who is actually ordering these tests. With the freestanding lab claims, we're able to identify the UPIN, the universal provider ID number of the ordering physician.

And, what we did is we searched for all the UPINs of physicians who billed for a Medicare capitation payment and we sort of loosely identified those as dialysis physicians or as a Medicare capitation payment practitioner in the terminology of the slide. And then we said for these various tests

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we've identified and classified into different clinical categories, what fraction of those tests were ordered by a physician that had billed a Medicare capitation payment for dialysis.

MR. AUGUSTINE: Let me point out, and the second bullet needs to be changed because it's, these are tests not billed by the MCP practitioner but by an MCP practitioner. There's a difference.

DR. HIRTH: Right, right. This is a much more inclusive list. Part of the difficulty with the provider ID is if the physicians are practicing

together in a group, we don't know necessarily is the UPIN of the specific Doctor going to necessarily attach to that specific lab claim for that patient. So this is, essentially if you're not identified as a Medicare capitation physician that means that you never billed a Medicare capitation payment for a dialysis management. So, it's as inclusive of a list as it could be. And just be aware of that in terms of interpreting the data. Yes.

DR. LAZARUS: I don't know that it makes

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any difference but John made the excellent point that the bottom six items there probably were not ordered by the MCP practitioner. He simply is a conduit because blood is available in the dialysis unit. I suspect if you would ask did he specifically order that and want it, you would get a different percentage.

DR. HIRTH: So essentially that practitioner would be nominally the ordering physician and that the labs were drawn at the dialysis unit but may or may not be managing the result of that test.

DR. LAZARUS: Correct.

DR. HIRTH: So for diabetes, the example that came up earlier, we see about four out of five of the tests that we had identified as relevant to diabetes care were ordered by an MCP as opposed to about nine out of ten. So, it's still a pretty high percentage but like you said we don't know who is actually doing something with that result. Interestingly, to kind of validate this approach, our nephrologist consultant, we asked him to come up with a name of a test that would clearly not be

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dialysis-related and then we wanted to see what fraction of that particular test was ordered by a physician we'd identified as the MCP practitioner. And, he said a Pap smear, and that was 3 percent. So, for that type of a test that sort of clinically seems very unrelated to dialysis, in fact, it was very rare to have that identified as the ordering physician being the Medicare capitation practitioner, so.

MR. AUGUSTINE: And that could have been, that could have been an internist who had billed MCP at one time, I guess, and maybe went back in practice and seeing someone who was a dialysis patient and then ordered a Pap. I mean, there's --

DR. HIRTH: That's entirely possible. Because, as I said, this is a very inclusive list of who is a dialysis physician. So, that's just a little bit of a tidbit in terms of validating that maybe there's sense to this approach.

MR. AUGUSTINE: Mike, when, Dr. Lazarus, when that happens, where does that test get performed, does that actually go back to the hospital or to

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whoever their independent laboratory is?

DR. LAZARUS: Well, because of the problems of reimbursement we prefer it go to the lab that they're affiliated with.

MR. AUGUSTINE: That they're affiliated with?

DR. LAZARUS: The dialysis unit is affiliated with.

MR. AUGUSTINE: Okay. Okay.

DR. LAZARUS: If you send it back to the hospital, they bill, you bill, then we have problems with that.

MR. AUGUSTINE: Well, do you, does that cause a problem with them not having the sort of privileges at your facility, ordering tests through your facility?

DR. LAZARUS: No. We send the results to them.

DR. BURKART: If I can just comment on that, I mean, I imagine it would vary from facility to facility. Some facilities may have a policy that for

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the lab to be drawn it has to be cosigned, if you will, or signed off by the capitation physician. And then you ordered it so theoretically you're responsible for it; however, you know, Mike, as was mentioned, the conduit for ordering tests for another physician and the tests, sometimes they draw the blood and bring it to the hospital but more often the tests are drawn and sent to the lab along with the rest but they're an ancillary test.

MR. AUGUSTINE: If you cosign it, that's your test.

DR. BURKART: I understand that. I was not debating that for one moment.

MR. AUGUSTINE: Okay. Okay. I just want to make a point clear.

MR. BURKART: I am not debating that for one moment.
MR. AUGUSTINE: All right.
DR. RUBIN: Paul?
DR. EGGERS: The reason we're looking at this table I believe is because only on the facility

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lab test is a UPIN identified but it's not, a UPIN is not identified on the lab tests from other facilities, is that right?
DR. HIRTH: Okay. On the freestanding lab claims the UPIN of the ordering physician is clearly identified. For those that come through the institutional claims, we're still taking a look at it in more detail but it's not, it doesn't seem as clear that we can identify the ordering physician on the -- so this refers essentially to the bulk of the 87 or 88 percent that came through freestanding labs are reflected in this table. It's the 20 or so million dollars that came through other, 25 million or so that came through other providers that is not a part of the data that are in this table.
DR. EGGERS: So this is most of the lab, most of that quarter of a million?
MR. AUGUSTINE: Billion.
DR. RUBIN: Billion.
DR. EGGERS: Quarter of a billion dollars?
DR. HIRTH: Right, which is almost 90

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percent of that.
DR. EGGERS: One thing, I don't even know if it's worth pursuing but let me just throw it out because it's in the back of my mind. If we're really sort of worried about what's ESRD and not ESRD, another way of looking at the lab bills would be perhaps just to kind of get some ICD9s there from the diagnosis.
DR. RUBIN: Have you ever tried to validate those? I write down the first three numbers that come into my mind.
MR. EGGERS: I didn't say it was the be-all and end-all.
DR. RUBIN: Okay.
DR. EGGERS: But there may be large categories, there may be large categories of ICD9 codes that, you know, you know, pregnancy, I don't know, what the heck, but something like that, I mean, there may be

things in there that, you know, help define this nonESRD that we're thinking about. We're looking at in terms of the test and in terms of the UPIN; why not look at it in terms of the ICD9?

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DR. RUBIN: Fair enough. Jay?

DR. WISH: My interpretation of this particular slide is that there are 10 percent of physicians who routinely take care of dialysis patients that don't bill under their own MCP, that they're not in their MCP universe but nonetheless they are seeing dialysis patients, they are doing monthly reviews of dialysis patients, they are transmitting orders to dialysis facilities to obtain laboratories but for whatever reason somebody else in their practice bills the MCP.

For the other tests like, you know, thyroid and seizure or perhaps not so much seizure but I suspect what's happening is that an endocrinologist who is following a patient for thyroid disease calls a dialysis unit and says can you get this test for me? And the dialysis unit says, yes, we'll do it, and we'll bill it under your name and your UPIN.

MR. AUGUSTINE: The point I made earlier, kind of which I guess cascades here, dialysis physicians are those that are a, an MCP and billed an

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MCP at anytime so those 10 percent are going to be people who have never billed an MCP.

DR. WISH: I think that's possible based on the way individual nephrology practices are configured.

DR. RUBIN: Okay. Go ahead.

DR. HIRTH: Okay. I think that's it for this session, discussion.

DR. RUBIN: So it is. So, to pick up on our themes, the issue here is what should the facility be responsible for, what universe of tests and/or drugs that are in addition to what I'm going to suggest is currently in the baseline under the composite rate do we want to include on the one hand and on the other hand is there any information that we would like to get that would help us make a better decision as to whether or not to include those services or tests or drugs as something that we would want to make facilities responsible for.

DR. HIRTH: One I thing I want to update

you on, it's the analysis that was suggested by Dr. Rubin this morning. We're able to get some of it run.

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We decided to do a 10 percent sample of patients. That's 2.7 million patients would have been, patient months would have been a little bit hard to go through in a matter of an hour but on 10 percent sample we just did for two characteristics just to make it a feasible run in the timeframe, urban versus rural. In the rural hospitals, rural dialysis units 67.3 percent of patients on HD had in fact a full month without an identified event. They had 12 to 14 treatments and no events identified.

For urban it was very similar. It was actually slightly lower, 66.2 percent. So, about 1 percent more identified events in urban dialysis units and patient months in urban units than rural. There was a bigger relationship with size. So, we looked at small, medium and large facilities, had the same cutoffs that are in some of the materials we captured. I think it's something like below 5,000 treatments, five to ten and ten or more, something like that. Small, 62.1 percent of patient months were full 12 to 14 treatment months with no events occurring. Medium

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was higher than that, 65.5 percent for medium; large facilities had 67 --

DR. RUBIN: I'm sorry. Could you go back? We had a little interruption.

DR. HIRTH: The small facilities, 62.1 percent of patient months --

DR. RUBIN: Right.

DR. HIRTH: -- were full months with no identified event; for medium, 65.5, and for large, 67.6. So, there was a reasonably significant, I would think, relationship there between facility size and the likelihood that your patient months have some type of an interruption.

MR. AUGUSTINE: An inverse relationship.

DR. HIRTH: Right. And when we go back to Ann Arbor we will do that for other facilities characteristics.

DR. RUBIN: Okay.

DR. HIRTH: Ownership status, chain status and any other standard set of things that we look at. I just wanted to give that quick data for now.

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DR. WOLFE: And Bob, I called Ann Arbor to tell them there's no way to get this done, don't even try and he said he had the answers almost ready.
DR. RUBIN: Okay, Bob. That's a good staff person. Anybody, Mike?
DR. LAZARUS: I want to ask you a question about how you we use the data. Your approach has been we will look at what's been done, assume that it's correct, and put that in the bundle?
DR. RUBIN: No. I mean that's not my --
DR. LAZARUS: Well, that's what it appears to be right now.
MR. AUGUSTINE: Well, Mike, if you could --
DR. LAZARUS: You're talking about data, where we have an opportunity to say, yeah, that's what's been done for the last thirty years but it's wrong.
DR. RUBIN: Absolutely. That's, I apologize for not being clear. That's really what I would like these sessions after we have seen what's been presented, this is the Committee's opportunity to
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comment on that information and in addition to saying that something may not be correct, hopefully the Committee can provide some constructive criticism as to how you get the right data or the right way to think about it. And then what I would expect from the contractor is that's a great idea, it will take us three years and fifty million bucks to figure out or what we just heard, sure, we can get you that in an hour.
And, so, because I think at some point, at least in my own mind -- and I'm just speaking for myself -- we're going to need to make some recommendations based on some rules. And, one of the rules might be if we don't have data that informs the decision we're just not going to put something in or price it into the bundle or whatever. On the other hand, we may say, well, it's not a big amount of money, and, if we're off by 20 percent doing some kinds of sensitivity analyses, it might be okay.
I mean, we might come up with all sorts of different things. But what I want to try to do today
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is at least expose what our concerns, anxieties and

recommendations might be as it relates to data. If anything I've said suggests that I believe that everything we've seen is spot-on what we need, I apologize, because that is, and they'll tell you that that's not what I believe.

DR. HIRTH: I think Nancy's comment about are there guidelines for certain tests, already very much in that vein.

DR. RUBIN: Jay?

DR. WISH: If I could put up a strawman based on what we've just heard, I mean, what we're trying to do is determine the bundle based on ultimately economic impact and best practices, to collect data to validate what we're doing so --

DR. RUBIN: And --

MR. AUGUSTINE: -- we have DOQI guidelines for anemia management. We have it for adequacy. We have it for calcium and phosphorous and bone disease. We have indicators at least for the adequacy and the anemia management, there's going to be indicators,

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there are indicators for bone disease and there are going to be performance measures developed that are going to be pilot-tested within the next year. And, we know that those are, in terms of their economic impact, the Vitamin D, Iron, EPO and then the tests associated with monitoring those things. So, that I think is a reasonable inclusive bundle to start with in terms of further discussion.

DR. RUBIN: Okay. Yes?

DR. OWEN: I have question. I have a question for Mike, as a large chain provider. How do you feel being the conduit for laboratory testing? And this returns to my second contextual question from this morning, and that is what is the site of service what is effectively occurring by what John has described, what I saw, what you lay out, the word is it a dialysis unit as, Bill Owen's opinion, rightfully become an extension of some physicians' practice and caring for the patient.

My concern for what Jay has described is the dialysis unit will be a site where care of end

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stage renal disease only is going to occur and part of the fragmentation of the system that I want to see go away in the management of a patient, a biographical

patient, not a biological entity.
DR. WISH: I said to start with. I didn't say final.
DR. OWEN: Let him answer his question first and then criticize.
DR. LAZARUS: Preliminarily we would like to accommodate patients. No one wants to see patients with a valuable resource, they can go get it stuck. So there is drive and a compulsion to provide service. However, if you put a bunch of tests outside the bundle, and tell me you're not going to get paid for those tests, I'm sure when the patient comes to get the test, we're going to say thank you very much, go somewhere else.
MR. AUGUSTINE: Well, let me say that also feeds into our Fistula First initiative. I am, treating these vessels quite delicately and letting the right people stick them so that they are protected are

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very important.
DR. LAZARUS: But you understand, that if you take the test you take them out of the bundle and you ask us to do it for free, then it becomes a problem.
MR. AUGUSTINE: I mean, I don't know, I mean, either it would be included in the bundle and that's the scope piece that we still need to talk about because you're still cosigning so they're your orders and you're billing them under your physicians' orders, if they follow the KDOQI guidelines, you know, succinctly then those may not be in the bundle.
DR. LAZARUS: But if they're not in the bundle, I don't care what the doctor does. If the physician says I want to accommodate the patient, and you tell me it's outside the bundle, there's no way you can, we think you're obligated to do this test, we did not include it in your reimbursement for the bundle, why, why would we do that?
DR. HIRTH: It's outside the bundle when it remains separately billable. I guess I'm not following

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your argument.
DR. LAZARUS: A separately billable component to this bundle? I haven't heard that.
MR. AUGUSTINE: I mean, that's what we need to talk about, those things that may be medically

necessary that are outside the bundle.
DR. LAZARUS: Oh. So we have the bundle and we can bill for an additional event --
MR. AUGUSTINE: Yes.
DR. LAZARUS: I haven't heard of that.
MR. AUGUSTINE: Well, there be may some things that are done predominantly like, for example, most things we're talking about are done 99, 98 percent of the time in the facility and 2, 3, 4 percent of the time elsewhere. There may be some things that are very rarely done at the facility and quite frequently done more elsewhere and those things may not be, may be outside the bundle and may be separately billable because we don't want you to incur a cost without receiving reimbursement but we would like to get as much as possible in the bundle to discourage as much

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gaming and to encourage as much efficiency as possible.
DR. RUBIN: Dr. Burkart?
DR. BURKART: I want to ask a question that goes along with that. Some of these things were put up there as an example of what is ordered so we can, here's the data, let's decide which one of these things we should include in the bundle. I believe that's why we have some of this up there.
DR. RUBIN: Exactly.
DR. BURKART: So let's use an example, hemoglobin A1C. Now, if we want to do the right think for the patient, we should be checking it and we should be reacting to it. So if it's included in the bundle my question to the group is something like hemoglobin A1C, we saw seizure or cardiac, if we move it to part of the bundle are we then mandating nephrologists to assume that part of the care? I think that's an important part of the question.
I'm not saying we shouldn't be patient friendly, we shouldn't be ordering the tests. I'm saying if we say since it's done so often as part of

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the bundle are we then saying nephrologists then are taking care of it. Now, if we order the test, it's our test to do. There's no argument there. But if it becomes part of the bundle, then there's a diabetic care, then the nephrologist responsibility, period.
MR. AUGUSTINE: And also it's a paradigm shift, though, as well because it could potentially

force practitioners and facilities to work more closely together because if that test is done in the doctors' office and it's in the bundle, they're not going to get paid or they're going to have to get the facility to potentially pay them and so it may force, in some of those areas where they should be working together it may force them to coordinate better, which is not necessarily a bad outcome. Nancy?

MS. RAY: I noted your point earlier about the potential for one payment bundle for both peritoneal and hemodialysis. I, for one, would be interested in looking at the differences in the use of services between hemodialysis and peritoneal patients. I think you had that one notion that you talked about,

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the one payment bundle.

I think the other notion is facing payment on the cost of efficient providers and rewarding for quality. And I, before we make, before a decision is made on that, I think as a first step we should look into the different, to what extent do services differ between modalities. And I guess the other issue I wanted to bring up is I see on the board, Part D, with a question mark.

MR. AUGUSTINE: Yeah. Well, I put that there to just kind of remind myself to talk about that because that's a potential issue here. In this expanded bundle there may be, let's say we include the Vitamin D, I mean, the Part B (phonetic) drugs that are injectable. Well, if when Part D comes online there may be an incentive for certain facilities to push people to orals like oral Hectorol, which in some cases are as good but in some cases they're not as good as the injectables.

And you definitely have the compliance issues. You know, it may be more harmful to patients

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and so we need to keep in mind how Part D is going to, the new prescription drug benefits are going to play into this demo because there will be incentives to get people onto orals which are not in the bundle.

MS. RAY: And I guess that was my next question. Statutorily in the MMA they cannot be in a bundle; could you clarify that, as far as oral?

MR. AUGUSTINE: The statute does not, I don't know if it -- can you read it?

DR. RUBIN: The statute doesn't say. The statute asks for this committee to talk about drugs and biologicals. It doesn't say Part B drugs, Part D drugs, it just says drugs. So, if we chose to put in the bundle phosphate binders, we could probably do that.

MR. AUGUSTINE: Let me, if I can read --

DR. RUBIN: Let me just finish.

MR. AUGUSTINE: Go ahead.

DR. RUBIN: My assumption is in reading in the context that it would be Medicare-covered services, not services that Medicare doesn't cover, but in 2006

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they will cover all drugs presumably that if they're used for their FDA-approved uses. So if we wanted to, at least I think, if we wanted to cover phosphate binders we could talk about DOQI guidelines and quality.

MR. AUGUSTINE: Well, that's why I put it on the board. Linda?

MS. LINDA: Just to alert people there is a report to Congress that CMS has been asked to prepare on the issue of transition of drugs that are currently covered under Part B to the Part D drug benefit since the benefit structures are very different, and since once there is a Part D benefit many drugs that are now currently provided virtually exclusively on an injectable basis, many of those will be available on an oral form and coverable under Part D. So this issue is being addressed more broadly even in the context of this. And I think we just have to keep that in mind as background.

MR. AUGUSTINE: And also as we continue to talk about patient-centerness, there's a big difference

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through our beneficiaries, whether something is Part B or Part D and that's something we're quite cognizant of as we do these research activities.

DR. RUBIN: Yes?

DR. WOLFE: I wanted to respond to Nancy a little bit about hemo versus PD. And, there are difficulties in measuring how many of these sources are given, partly because for a lot of the PD patients we suspect that many of the drugs are given orally instead of IV.

We see a much lower utilization of drugs

among the PD patients. That's not because they aren't being given, it's because they aren't in the bills and we don't see them. We suspect, it's also true that I think, it's my understanding that less EPO is needed for PD patients but it's not nearly as much less as we actually see in the bills. So, it's difficult to give a direct comparison from the data of PD versus hemo for the drugs which is the bulk of what we're talking about as Paul has pointed out.

MS. RAY: Right, but that's precisely my

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point. I mean, if we were to think about the notion of basing payment based on the provider's costs, if the provider is not giving the drug as an injectable, if it's being given as an oral, then I would have at least liked to know the disparity between the use of injectables between hemodialysis and peritoneal.

DR. RUBIN: Okay. Good point. Go ahead.

DR. BURKART: I think in the old system before January 1st, where part of the excess revenue for providing services to a patient with ESRD came through using drugs. You know, there was a move to make sure that hemodialysis patients got the drugs, number one, versus the peritoneal dialysis patients and also part of the money that you made perhaps to do what it costs you to do hemodialysis came from that. As we move towards a composite rate that takes care of the cost of doing dialysis, of providing care to the dialysis patient, and take away part of that excess revenue coming from the drugs, I'm not sure that we need to say should we, do we need to look at the differences between PD and HD because it could be that

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in HD you would provide the drugs orally, too, some of them.

I think that the key thing there is that you have an indicator that makes sure that the treatment is being given and that we are trying to get to patient-centric outcomes that are good. Okay. So if we, for instance, we could give oral Vitamin D into a hemodialysis patient. We could if we wanted to. And, it may work just as well, or, so, but, so I think if we change this, if we move away to having payment separately for their drugs and its bundled, I think it's okay to have the payment be the same for both modalities as long as we are held accountable for

making sure that we achieve the outcomes that that money is paid for in our patients.

You can give, some of these things could be done orally or IV. And if we look at the difference between services right now, I don't know that we can tell for sure what is driving the difference in one group of patients versus the other. The PD patients may refuse to come in or they may not need as much or

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the administration may be motivated by the excess revenue that you were getting in the drugs before January 1st of this year.

MR. AUGUSTINE: Paul?

DR. BURKART: Did that make any sense?

DR. EGGERS: At the risk of vastly increasing CMS staff responsibilities and headaches, as I listened to some of the discussion about the way various dialysis facilities operate, and, you know, what they are and aren't responsible for, is it possible that we could even go so far as to recommend two or three or four different bundles of increasing amounts or something like that and facilities or whoever bids on these sorts of things, however the demonstration is to work, could opt for one or more. I mean, suppose that you had a group of facilities that really did want to take responsibility for, they agreed they could take responsibility for diabetic care and they wanted to receive, they wanted to get paid for hemoglobin A1Cs four times a year, they will do that, put them in the bundle, they will take care of it and

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the others kind of say that's not our job, we're not going to do this, we would like a bundle that doesn't have that.

MR. AUGUSTINE: I mean, the issue I would have with that is it's not a very holistic approach unless it becomes a boutique facility where they primarily treat people with diabetes. And we would like to have something that's a little more holistic. One thing I did want to get back to Nancy on, and we tried that with the last demo and we will see soon what the results of bifurcating the RFP (phonetic) and the disease management demo, what the results of that were. Nancy, getting back to your comment about the efficient, you flow, provider, one issue that going to be tough in PD are that a lot of the patients today

from my understanding -- and clinicians, I think you echo this -- that they get orals that are not Medicare covered so we don't have any data on them. So, what you will find out, if someone pulls PD data, it's going to look a lot lower than it really is for what it would be in 2006 when we do cover those orals.

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DR. RUBIN: Bill?

DR. OWEN: I'm going to join Paul and be a curmudgeon because I actually was going to raise later on maybe there is a duality approach to this because one size does not fit all. You know, one of the very striking things that Mike Lazarus and I were talking about earlier today was when we were both practicing there in Boston and he had the uptown unit and I had the downtown unit, and we're talking about units that were five miles apart and I will tell you --

DR. RUBIN: Does that mean I had the midtown unit?

DR. OWEN: There you go, baby. But the patients had very, very different needs and I put on a hat from North Carolina where we have a lot of rural units and a lot of rural patients. It just ain't feasible to be able to go out and have concierge dialysis. The patient has got or should I say it's not feasible but it is needed. The patients don't have the luxury of being able to float around to get bunches of tests done by others outside the unit.

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So, one size does not fit all and I do recognize the need of simplicity and certainly, you know, we talk about values, the inherent value of having a single system administratively but I do think it is reasonable to consider and since we are using this as a Beta test to consider a Beta test in which we compare the two, to meet the two extremes and needs.

MR. AUGUSTINE: Well, are you asking about like a stratified approach? I mean, it sounds like you're arguing for maybe even a more comprehensive bundle. So that's not necessarily different bundles unless you want to have one that's very sparse and one that's very comprehensive.

DR. OWEN: Exactly, one that's sparse and very comprehensive. And I will, you know, perhaps speak out of turn and will say that, you know, wearing a physician hat, one of the conversations that has been

occurring in the Renal Physicians Association in terms of looking at what our next payment model might be is how to recognize that there are some guys who are out there, who are very good and very comprehensive in
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their care and want to be the physician in general and others who say, look, I'm just really good at dialysis and I just want to do dialysis and can do that very, very well.

DR. RUBIN: Okay. I think actually the charge suggests that we would take cognizance of geography in designing the experiment, so to speak. So, that might deal with some of your issues in terms of the access. It doesn't really get to the heart of a point you have made several times today, which is, what actually are the expectations not only of the facility but of the physicians that practice in that facility.

And I think, and to a very large degree the physician component is rightly or wrongly off the table. We're not talking about the MCP; we're talking about the bundle. And, so, the issue here is what do we want to hold facilities accountable for and what do we want to include and do we need more information. You know, so far we have been a little schizophrenic on that, to say the least.

DR. OWEN: If I might just respond back.
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You know, I recognize that the physician is off the table but as those of us who have been medical directors will clearly say, it is a strong interdependency. They are linked together. You can sit there and argue and legislate as much as you want but they are, one's off the table or not but I can set up a system and make the physician work very well within the unit and then likewise a physician can confound anything that I try to do within the unit. Now, I would be very interested to hear what Dr. Lazarus who oversees hundreds or maybe thousands of units of medical directors has to say about that. So, I guess what I'm saying is, that at the end of the day, ideally what we want to do is to develop a system that facilitates the physician working with us.

MR. AUGUSTINE: Yes. Bonnie?

MS. GREENSPAN: Just to clarify for myself, what I heard Paul saying about providing the hemoglobin A1C for those patients in the facility that were

diabetic didn't seem to me to be boutique-wish, it seemed holistic for all the needs that that group would
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have. Not everyone there would require that. So the percentage of patients that we anticipate being diabetic would, that would generate the kind of numbers for it but that didn't seem boutique to me, that what I thought you were suggesting was a split for those who were willing to have a more comprehensive --
MR. AUGUSTINE: So yours wasn't stratification, it was more scale like Bill and I were discussing?
DR. EGGERS: Well, actually, I had given it a good five minutes of thought so I clearly haven't worked out all the details on this but --
DR. RUBIN: That's more than usual.
DR. EGGERS: Huh?
DR. RUBIN: That's more than usual for government programs.
DR. EGGERS: Absolutely, absolutely, just take that out of the file sort of thing. No, I mean, you know, apparently we're going to talk later about the possibility of vascular access. I mean, that's one that, you know, certainly raises that question even
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more, as to whether or not a facility wants to somehow incorporate that kind of payment. I mean, you know, I picked a relatively pretty small one but they're, you know, I don't know, it just, it just, I don't, I don't have a, well, I don't know, maybe, it's even something, we haven't started to talk yet about case-mix but if you think about, you know, case-mix can even sort of drive that sort of thing in that --
DR. RUBIN: Right.
DR. EGGERS: -- you know, the payment, you know, the presence or absence of that characteristic in the population, in the thing can sort of drive the payments and such.
DR. RUBIN: Yeah. Other comment? Is a there comment down -- yes, Nancy.
MS. RAY: Yes. Let me just follow-up on the modality point one more time. I think it's important as we go towards a broader bundle to understand what Medicare is paying for in the broader bundle and what providers are furnishing and potentially what Medicare is paying for and maybe

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providers aren't furnishing because patients are getting it through Part D. And I think that is what's leading me to want to have a better understanding of at least under the current, under the 2003 payment system, to what extent are the use of injectables in laboratories different between hemo and PD patients.

DR. WOLFE: We'll get it for you.

DR. RUBIN: Okay. Other comments as to what the facility needs to be held accountable for? Anybody? Yes.

DR. LAZARUS: You've said the MCP was off the table. Is it absolute fact that we could not say we think the MCP should be or recommend it be brought in to be part of this?

MR. AUGUSTINE: It's not exactly within our scope but I think it's, this board can make all the recommendations we want. That's something this board agreed upon. You could put a footnote at the end of the paper or recommendation saying we believe incentives should be aligned and I don't think you'll receive any agreement.

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DR. LAZARUS: It will be very hard to not make this bundle as narrow as possible without physician participation and alignment.

MR. AUGUSTINE: I think everyone, unless someone else feels otherwise, I believe we're all in agreement that incentives need to be aligned.

DR. RUBIN: Okay. What I think I would like to do is, it's about 7 of 3. I would like to adjourn until 3:10 and then we'll start up with the last piece of the design, talk about case-mix and leave some time for public comment and then next steps.

MR. AUGUSTINE: Again -- sorry.

DR. RUBIN: Go ahead.

MR. AUGUSTINE: Since, you know, I made the announcement earlier if there was anyone from the public, you know, out in the audience that would like to talk during the public comment session, please, I've got the paper right here, put your name down so we can have an idea how many people are interested.

(There was a break in the proceedings.)

DR. RUBIN: If we could take our seats and

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get back. If we could come in and take our seats, we

could get started. We might even be able to leave early so we could all beat the traffic home. All right. I think that the next, the last area that we want to talk about in terms of payment design is to define the unit of payment -- and, great, we're back on, the slides. Thank you.

So, the critical question, next slide, is what's the time span that we want to have covered by the payment, is it a single dialysis, is it a week, a month, per annum, whatever. And, I think that what you can see from the sort of the distillation of what the committee said this morning, are that there are the six -- I think it was -- yeah, the six things that people felt strongly about was that the time span needed to be sufficiently so that there was the ability to be flexible in a way that was consistent with both the patient's wishes and the clinical realities of treatment.

And, ideally we wanted to be able to have a level playing field relative to different modalities of

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care and ultimately different sites of care, home versus center. So, if we can go to the next one. I think I have already gone through that. I think that the issue here is picking a time span or a unit of payment that makes sense and deals with some of the vagaries that we talked about at the end of the morning session, got a brief update earlier this afternoon and now we need to take a more careful look at. So, with that, why don't we continue.

DR. HIRTH: Okay. This repeats the slide you saw this morning that had the typo in it. In your notes the second bullet should read nearly 3 out of 10 as opposed to 7 out of 10. So, the typo was repeated along with the slide. Essentially this will refresh where we were this morning. Looking at all dialysis, nearly 30 percent of patient months have some type of an event that might interrupt the full month of dialysis. Some of the common causes were hospitalization, start-up and death and we have more detail and data on those causes.

So, if we classify all patient months into

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groups, the first two, that's 71 percent without a month, without an event, could be called up, classified into full month HD and full month PD. So, those are 71

percent of patients that had 12 to 14 treatments per month and had no indication in the data of being hospitalized or having any of these other identifiable events occur. The rest the slide really gives a much more detailed breakout in terms of what happens when there is an event.

And it's useful to compare that in terms of separately billables to the full month with no event. So, for example, the HD full month no event had about 13 sessions per month on average and about $900 in separately billable allowable charges. So on a per session basis that's $69 of separately billables per month for those that had their full complement of treatments and did not have any type of an identified event. For PD a little bit of data, to go to Nancy's question from before the break.

The separately billables are only about a third as high so if you look at the full month PD

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versus the full month HD it's only about $300, partly because there are many different utilization patterns for things like EPO that are paid for and then the other drugs that are given orally to PD patients and therefore don't show up in the Medicare claims which in effect patients are paying for them.

In terms of the events, I'd really like to you focus on the first two, to start out with the hospitalization, that was the most common type of an event. The next most common was what we call the unexplained partial month. The unexplained partial months are those that had less than 12 -- but we did not identify a specific event.

So, what we speculate is that a mix of months where patients had skipped treatments, and possibly some people starting dialysis on a two times per week schedule rather than a three times per week schedule. That probably would account for most of those months. And, what's interesting about those top two categories is if you take a look at the separately billables per month, they're almost spot-on o the full

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month, no event. So then when you divide that number through by a much smaller number of sessions, obviously on a first session basis it's much higher.

So, essentially the patients who are hospitalized or have short months for unexplained

reasons seem to still be getting sort of their full comment of separately billables for the month, essentially a catch-up phenomenon probably where if you skip some treatments, you have to catch up on your other, your lab tests and your other injectables. So that seems to be happening here. So, those on a per session basis, months that have those types of events are much more expensive.

MR. AUGUSTINE: Clinicians on the board my understanding is there's it may be explained by the fact when you're hospitalized the DRG kind of covers the EPO. They only get separately for it so there's no incentive for the hospital to provide EPO. They come back and just maybe double-up.

DR. WOLFE: That's what he said.

DR. HIRTH: Okay. Right.

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DR. LAZARUS: Are these all drugs, this charge, the service is drug; what are the charges?

DR. HIRTH: The same separately billables that we looked at before, just drugs and labs.

DR. LAZARUS: Drugs and labs and that's all?

DR. HIRTH: Right.

DR. LAZARUS: Emergency room.

DR. HIRTH: No. The same things we had been talking about in the earlier part of the presentation.

MS. CUELLAR: I just have a comment to the thing that you said that the patients are paying for it themselves. That's not necessarily true.

DR. HIRTH: They might have a secondary insurer.

DR. EGGERS: No. They may not be buying them at all and not taking the medication even though it's prescribed just because it's over the counter.

DR. HIRTH: We can't determine it here from the claims because we simply don't observe what they're

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doing.

MS. CUELLAR: Right. Right. So it's not necessarily that there's a substitute to the injectable.

DR. HIRTH: Right, right, right. The key is that Medicare is not paying for it.

MS. CUELLAR: Right.

DR. HIRTH: Okay. If you look at some of the other causes of short months, short terms, number of treatments, they don't have that pronounced of an impact on the separately billable costs on a per session basis. So, if you look, for example, at patients that transfer between facilities, the third category -- on average you'd have just a hair over two facilities per patient because the vast majority who switch are just going to be a two but there is occasionally somebody with more than two. So just as a rough guide. If you got a -- we haven't done this on a per patient level. It's on a per patient facility level for that.

So, as a rough guide if you double that

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number you get a 12.4 sessions per month so if you a little more than double it you're up to 13. And then you take the separately billables. If you double them and maybe a little hair more, you're right back at the $900. And on a per session basis $70 versus 69 for the full month HD so the patients who are switching facilities during a month seem to be consuming separately billables at kind of a comparable rate and attaining sort of the same level of treatments on average as patients who had a full month without any event.

What we haven't done is break, broken out to see, say if it's a transient dialysis case where you are traveling for a few treatments and then you come back to your home facility, do the separate, does the separately billables spending per session different in the transient facility versus your home facility where you might not be getting.

So, at least on average it looks like these patients over their whole month look pretty much like the full month HD patients. But that doesn't mean that

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if you look carefully at where they were getting within that month their separately billables you might not find some patterns.

So, the others are sort of intermediary. I won't spend a lot of the time talking about them. If you look at the last column, the first session amount, patients who die in the month have certainly higher spending on a per session basis. For the sessions that they did receive, then the no-eventful month patients,

kind of comparable to the hospitalization patients, on a per treatment basis, starting dialysis. Also, there seems to be a higher cost on a per session basis at start-up probably as you're getting their EPO dosing stabilized and getting their anemia under control. Those who receive transplants in the month actually look very similar on a per session basis to the full month, no events.

And any other training sessions I would imagine is somewhat dominated by PD relative to some of these other categories and that probably explains the lower first session. And, switching modality also

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seems to be pretty comparable on a per session basis. So, essentially there are some types of months where it seems like prorating by time is a fairly straightforward thing to do and probably doesn't have any dramatic implications.

There are other types of events or other types of months where, say, if a patient is hospitalized for a week and you then prorate it, a monthly payment for that, to account for that week they're out of the hospital, that essentially you would be underpaying the facility for the separately billables that are being delivered because even though the patient is gone for part of the month and not getting all of their dialysis, they are getting what looks like a comparable amount of separately billables to those patients that were hospitalized. Any questions on that before I move on?

DR. BURKART: I just have a question regarding the data. In my personal practice, though this is anecdotally, maybe 5 to 10 percent of patients are on more frequent dialysis, so, daily in-center or

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daily home, or four times a week dialysis. So, if you have a hemodialysis patient that is in one of those categories how is that picked up in this? For instance, if they're getting daily dialysis and they went two weeks as an outpatient and got 12 treatments or two and a half weeks, and, you know, ended up with 15 treatments but, within hospitalized, are they recorded as an event or not an event? And then is that, is their dose of medication average still per month or per session; how do those patients get included or excluded in this stay?

DR. HIRTH: Well, this is one area where there's certainly a limitation in the data because we are based on Medicare claims and since Medicare only reimburses for three times a month, it's really difficult if not impossible to accurately observe which patients are getting more frequent hemodialysis than the schedule for which Medicare reimburses. So, they will be essentially mixed in with the three per week. They would look, to us they would look to just like the standard three times a week dose because that's the

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number of paid sessions that they would be getting.
MR. AUGUSTINE: Let me clarify. We actually pay up to four at the contractor's discretion.
DR. EGGERS: That's right. So, in your case it would look to the data system like they were getting four times a week dialysis?
DR. BURKART: Yeah.
DR. HIRTH: So four times a week we would have a small amount. We restrict it to months with no more than 20 paid sessions. That wasn't a very important restriction, that's almost no months, in excess of twenty -- and for four times a week it would still be under that. It was a very small prevalence of months with more than 14 treatments.
MR. AUGUSTINE: So, John, what you're saying, what it's saying, if I can summarize correctly, that these patients may show up as four times every week but they may actually have three weeks of treatment four times a week and look like they didn't have an event when they really did and they were out in the hospital.

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DR. BURKART: Right, that was one, and then of course if we're going to the unit of payment is per treatment or per week or per month, you know, how would we deal with that, so.
DR. RUBIN: Right. Mr. Hirth?
DR. HIRTH: In terms of the with or without event, in this slide we actually, I think this goes to your question, we classify patients simply on whether or not they had an observed event. And, if you look at the dark green bars, pretty much trails off at 15 treatments in terms of being discernible within the scale of the bar graph obviously in terms of having any substantial percentage of patients, 15 treatments per,

paid treatments per month is where the data kind of maxed out. So, that's among those that had no measured event.

Among those that had a measured event, that's the light gray bars and there we see as we expect the number of treatments is much more broadly distributed rather than being sort of tightly peaked in the 12 to 14 range. So, typically utilization of 12 to

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14 represents about 79 percent of the months. So in terms of classification with or without event, it means there's still some, there's some people that are classified as having event that still have 12 to 14 treatments per month.

So, that's a distinction between that. So, 79 percent being in the 12 to 14 range versus the earlier pie chart which said 71 percent on a full month with no event. So, essentially there are about 8 percent of patient months that are in the 12 to 14 range but nonetheless have some measurable event in them. So you could be hospitalized for a short period of time in the month and still get 12 treatments. So, there, we separately classify based on whether or not you had an event and the number of treatments received. Because we don't infer that if you had 12 to 14 sessions you necessarily didn't have an event.

And this just looks at the kind of the wide variation that occurs in months where there is an event as opposed to the very peak relationship in months where this is an event, just kind of makes the data on

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the last slide a little more clear by putting the with-event bars in the discernable color on the slide as opposed to the gray background. And, I won't really say anything about this but this is just repeating the data that was in the table about three slides ago and looking at the different types of events that occur and what the separately billable payments are in months that have those events.

MS. RAY: Could you go back? Okay. Can you explain what the hospital 880 dollar bar means? I'm sorry. I would like some clarification.

DR. HIRTH: Okay. That's the same data that appeared on this slide, which is that in months in which a patient was hospitalized, what was the total separately billable drug and lab charges for that

patient. Yes.
DR. LAZARUS: Those events on there that occur in which the partial month had to be before the event, death or transplant, why, I can understand maybe in a death why there would be more maximum charges, maximum allowable charges but with a transplant I don't
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understand why. They get called out of the blue. Why would that category have spent, what is it, $403 per month? If you don't know they're going to be transplanted, they get called, the rest of the month they're gone so if all of those expenses had to occur before, why would that group of people have had those extra charges and extra services?
DR. WOLFE: They didn't have extra charges.
DR. HIRTH: The charges look exactly like the full month HD. They've got, on a per treatment basis it's $65.
DR. EGGERS: That's half a month's worth of dialysis. I'm sorry.
DR. HIRTH: Yeah. They got on average 6.2 sessions. If you divide that, divide the $403 of separately billable charges they received for that part of the month until they got their transplant by the 6.2 sessions, they got $65 per treatment of separately billables compared to $69 in the full month HD. So they look very similar.
DR. LAZARUS: I don't understand the chart
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then. This is not extra charges, extra lab, extra drugs? This is just a different way you averaged it.
DR. HIRTH: This is just the separately billables that were billed by the dialysis facility and by other providers during that month.
DR. LAZARUS: I still don't understand why they would have had them.
DR. WOLFE: They aren't getting extra payments here. This is just typically if you get a transplant you're there for about half a month and the charges are half as much because of that. So, you're just accumulating charges at the regular rate until the transplant and then they stop.
DR. LAZARUS: This, at least as I interpret this, this was extra? No?
DR. WOLFE: No.
DR. LAZARUS: Okay.

DR. HIRTH: This is just your EPO, your Iron, your Vitamin D and your labs in this small amount of other services and supplies. So they're accumulating them at the exact same rate as the full

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month, no event people.

DR. RUBIN: Just to follow-up, is your question what happens to all of those tests that are done that are separately billable to Medicare that relate to the process of transplantation and where they would show up?

DR. LAZARUS: Or any of the other categories.

DR. RUBIN: And that's somewhat surprising.

DR. EGGERS: What tests related to transplantation?

DR. RUBIN: Well, there's a whole slew of things.

DR. LAZARUS: A whole slew of things.

DR. RUBIN: Of the immunological tests that get done prior to a transplant.

DR. EGGERS: I thought that was part of the acquisition costs, they get billed, in a pass-through amount that the hospital adds onto the cost report.

DR. WOLFE: This is just the EPO, the Iron, the Vitamin D and the labs. That's what we're counting

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in this particular slide.

MS. GREENSPAN: Not the transplant.

MR. AUGUSTINE: Just those top ten labs or all of them?

DR. WOLFE: The top 50.

DR. RUBIN: The top 50, okay. All right. So, in this final piece of the design sessions, I guess the fundamental question is, is there any more information that we need to informed choice as to the time unit for payment and are there any sort of unintended consequences of going or positive things about going to a unit of analysis longer than a single session?

DR. LAZARUS: I'll build a scenario for you. My fifty dollars, units, and I sign up for the bundle and I decide all my patients, I will dialyze them ten times a month, and on the day that I check my EKD I will be able to dialyze them six hours each. So I have excellent outcomes. I reduced my dialysis times

three per month. How are you going go from gaming the system? My answer is obviously is you have to measure
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adequacy, you have to measure the full run every treatment. Now, not everybody can do that. Some of us can but not everybody can. But how are you going to keep from gaming the system when you a monthly --
MR. AUGUSTINE: Let me -- that incentive exists today.
DR. LAZARUS: No.
MR. AUGUSTINE: I mean you could, there's no real guard against ensuring people today.
DR. LAZARUS: Yeah, but I don't get any card punched about whether I dialyze 10 times or 13 times or 8 times. I get paid for treatment.
MR. AUGUSTINE: All right. Okay. I got you, but, the one good thing, well, actually, the conditions wouldn't help out here because conditions are based on the KTRV.
DR. LAZARUS: You have to measure adequacy for every single dialysis, you have to you have a monthly KTRV.
MR. AUGUSTINE: I mean, just like with the MCP, which is somewhat contentious at times there is a
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requirement that they put on there the number of visits or interactions with the beneficiary. There may A monthly bill for the provision of dialysis or management of dialysis and which included at least so many treatments.
DR. LAZARUS: Well, that still doesn't tell you that you are delivering adequacy. I have to measure adequacy. If you're going to do this you have to measure adequacy. I mean, it's like me saying well, I could say I did 13 dialysis treatments but I'll do one hour for 12 of them or ten of them or six of them.
MR. AUGUSTINE: One thing I want to remind everyone, if I am correct, if someone in the audience that knows, Pam, better than me, please say so, but the current composite rate pays for 13 BUNS, 13 adequacy measurements. Some people aren't doing that but they are being paid for it.
DR. LAZARUS: It's per quarter.
MS. CUELLAR: Quarter, quarter.
MR. AUGUSTINE: I'm glad I got corrected.
DR. LAZARUS: I'm sure it's a quarter.

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MS. CUELLAR: Yes.
MS. GREENSPAN: If you look in I think.
MS. CUELLAR: And that includes --
DR. RUBIN: Kris?
MS. ROBINSON: I have to agree with Mike because at the opening I said, you know, with the question what are the three key things the bundle must have measurement, measurement, measurement and if we don't measure, it's the patients who are going to lose out in the end. There's nothing wrong with putting it on a monthly rate but we've got to ensure that patients are being adequately treated during that month.
DR. RUBIN: Jay?
DR. WISH: If there's one alignment incentive more or less that exists in the current system, it's keeping people in their chairs and getting them to come to the unit, not in the hospital, not skipping treatments, getting them into the unit. I think if you had a wider bundle in terms of the unit of payment would misalign those incentives because the facility would get paid for the equivalent of 13
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treatments regardless; however addressing the second question, I think the bigger the bundle the more you could justify increasing the unit of payment to allow for experimentation for different types of dialysis in terms of more times a week or longer treatments or things like that.
I mean, if you look at the CHAR experience in France, I mean the longer treatments were clearly associated with total lower costs because the patients require fewer hypertensive medications, fewer phosphate binders, less in the way of EPO. So with a big bundle then I think you would encourage that kind of out of the box thinking and perhaps decrease lower costs and increase the margins from the facilities.
DR. RUBIN: Could you tell us what you mean by a big bundle versus a little bundle or --
DR. WISH: Well, a big bundle that included those things that CHAR, for instance, show could be saved, you know, not only EPO but the phosphate binders, the antihypertensives, a lot of the other things that end up costing the total system if not just
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the bundle part of the system.

DR. LAZARUS: You want to do this without the physician being able to consent?
DR. WISH: I'm sorry?
DR. LAZARUS: Do this without the physician being able to consent?
DR. WISH: Well, the one lack of alignment in the antihospitalization incentive is the physician who said it's almost aligned to keep people out of the hospital in chairs. The one person who is not in the current alignment is in fact the physician who potentially earns more money when the patient is in the hospital. So, I think in any system you have to align the physician, the current system or any proposed system.
DR. RUBIN: Paul, did you have a comment?
DR. EGGERS: Well, I actually was going to ask a question that Jay started to answer which is Mike has given a pretty good example of the downside, and I was trying to think of what are all the upsides. I mean, the ability to be more flexible, you know, we

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sort of all mentioned that at the very beginning but if we thought of say, two options, one being it's still a payment per service but it's a larger bundle for the service, what is the added flexibility that could be done there, what that might get us. If you went to a weekly one, then what would be the advantage there.
And, I mean, I'm not a physician and I don't work in a dialysis facility so I hesitate to suggest what those might be but that's how I'd phrase the question, I guess. How would a medical director come and look at that and think, gee, if I had one payment per week for that patient, what could I do, that, you know, thinking outside the box.
DR. LAZARUS: I don't think as a physician we think in weeks. I don't think in weeks. I maybe think of months when I think of sessions but I certainly don't think in weeks. I don't know if other physicians here think differently. The other thing is we have to get away from months. As you calculate, many things that we need to calculate we need 13, 20 and we need 13, 4 -- what am I trying to say?

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Four-week sessions, not 12 months. The months are different. They vary. If you're going to do this, you need 13 four-week sessions.

DR. RUBIN: Okay. Anybody, Dr. Burkart?
DR. BURKART: Well, how might you minimize some of the downside risk is if you actually had part of this pay-for-performance in effect. I mean, in your example, Mike, I mean, we could do that and we could get the bundle payment but if that happened, some of the other indicators for the patient, which I know you know, the hemoglobins might drop or the hospitalization might --
DR. LAZARUS: Just for EPO dose, though.
DR. BURKART: Yeah, the EPO dose. All of those other things might not be as good so if you are also if there was a pay-to-performance tied into this, you wouldn't want to be doing that because it would adversely affect your payment or you wouldn't get the extra, whatever way that goes.
MR. AUGUSTINE: Let me also add that the conditions even though that specific part where it

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talks about having a minimum KTRV may be able to be gained. You know, I don't expect that would last for long before there would be a state surveyor in that facility looking at standards of care.
DR. LAZARUS: Where does it say per month in the standards of care? It doesn't say.
MR. AUGUSTINE: Well, I'll leave that up to them but I believe that there would be some issues that would arise very quickly and they would look into it. I don't know exactly how they would address it but --
DR. LAZARUS: It would much easier that you measure it properly.
DR. RUBIN: Tom?
MR. CANTOR: It just seems that the concept of the bundling is a responsibility, an increased responsibility for the recipient. And to go along with that has to be an increased accountability. And so we have to be cautious about taking away measures of accountability. For example, although it may seem burdensome to have the unit of measure be the session rather than time, it still is a measure of

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accountability which at least in my mind seems to be necessary because the balancing here that's trying to be done is to make provision for outside the box or innovative, new modes for caring for the patient but at the same time caution has to be exercised to not

abandon accountabilities.
MR. AUGUSTINE: One thing, I don't want, just like the situation we had today where paying policy drives practice patterns. I mean, I know there's a lot of talk out there about middle molecules and I'm getting way beyond my depth but about shorter, more frequent or maybe fewer but longer. I mean, there's a lot of discussion out there about what's the appropriate frequency and duration. And you know, I want to make sure we strive a good balance so that the payment policies are driving things but allowing people to innovate as they see fit.
DR. RUBIN: Nancy?
MS. RAY: Yeah. I'd also, would perhaps a monthly payment bundle be more conducive to including, I guess what we call non-ESRD services into the bundle,

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like hemoglobin A1C which is, I guess, supposed to be done once every quarter --
DR. RUBIN: Right.
MS. RAY: -- or cholesterol tests or things like that. I mean, as we think about the timeframe of the bundle we should think about the non-ESRD services as well.
DR. OWEN: You know, Mike, I'm not dismissing your concerns because I think it's reasonable but I would argue that virtually every manager, you can come up with some sort of sinister behavior that would persuade that you that it wouldn't be reasonable to pursue, you know.
DR. LAZARUS: This is an easy one to do that.
DR. OWEN: Well, I'll give you another easy one, Mike, hemoglobin. You know, if I say fine, you know, I'm going to save somebody on EPO because I'm going to inject them full of antigens and give them lots of Vitamin C, and they'll get oxylosis six months from now. I'm not worried about it. I mean I would

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say virtually everything you can think of you could think of some sort of sinister behavior. Maybe I'm being Pollyannish about this but I, you know, it doesn't dissuade me. I really have, I have trouble believing that en masse we're going to go have even a substantial minority behavior that's going to act like that. Might there be some jackass who is going to be?

Of course, there always is one but --
MR. AUGUSTINE: Get that in the transcript.
DR. OWEN: Oh, you can quote me in the transcript for that. Feel free to do so. But, you know, on the other hand, I think the advantages of having a payment of a month and the ability to be innovative in terms of how I offer care outweighs my concern about, you know, what's going to happen because of some bad behavior by a very small minority.
DR. LAZARUS: Well, I don't, I think Jay gave a better example. It's going to be those people en masse, we're not going to go after the aggressive -- it's very easy to say, but look, I'm not going to chase that around. I got too much to do here. So, it will
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be inadvertent, it will be minor. I guess my feeling is more than anything else, we have to have a better measure of dialysis adequacy, if we're going beyond a single session, a monthly measure.
DR. OWEN: Perhaps I'm misinterpreting what you describe. You know, what you are describing to me sounds like an ethical, moral issue and you can get the greatest group sitting around the table, you aren't going to be able to legislate or regulate that. That's something that's learned from your patients and that you acquire as you go through your professional training.
You know, again, maybe I'm dismissing something that's not there. You know, if I know as a practitioner and I describe a practitioner here as physician, nurses, allied health professionals all involved in the unit, that it is bad for my patient to miss mistreatment, I would hope that as a professional whatever sort of suffix I might have in my title that I will go after that patient.
DR. LAZARUS: There are a lot of doctors
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that believe that two times per week dialysis is adequate.
DR. OWEN: Then that becomes an educational issue if that's the case. That's not a regulatory issue or payment issue.
DR. RUBIN: Well, let me sort of pose the question to you. If you are to expand the timeframe to a month, is there any more information that you would like that would make you more comfortable in doing

that? I mean, that's really, I mean, our assignment today is to give some homework to the folks at Michigan to find, you know, so that they can empower us to make good decisions as it relates to constructing this bundle. So, it seems to me that what we have seen presented is a description of the status quo which is payment per treatment.

And, so, my question to the group is if you think that we're going to expand the unit of time, are there, is there data that we need to make an intelligent choice? Mike's mentioned one of them a few times, which is we need to think of, see whether we can

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get an adequate measure of, a good measure of dialysis adequacy. Are there other sorts of things that we want to have Bob Wolf and his colleagues look at.

MR. CANTOR: Bob, if it's possible to look at patients, to identify the patients that had as has been brought up two times per week historically and attract the hospitalizations and mortality on those patients.

MR. AUGUSTINE: I remember culling through a very large database and finding out of 50,000 patients, I mean, not more than twenty or fifty, I mean not more than that were on two times a week.

MR. CANTOR: Well, that's what the current is.

MR. AUGUSTINE: It's quite rare and mainly those who still have -- again I defer to the clinician -- a residual function.

DR. RUBIN: Yes.

MS. GREENSPAN: Just one other comment about the missed treatments that I think is probably the truest thing that we would be concerned about. If

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we use an historic base that includes the missed treatment ratios we have, reducing missed treatments, and that's the basis for the bundle, then reducing missed treatments would actually cost you money because you would have patients there using supplies and personnel. And, so, if you did it based on a month instead of on a per treatment basis and you reduced your number of missed treatments, you would actually get less for the treatments you did give. So that's not a very positive thing either.

DR. RUBIN: Okay. Anybody else have any

comments about information that we may require to go forward to expand the timeframe? I'm sorry. Go ahead.

MR. AUGUSTINE: The one thing I would like to understand better, I don't have all the answers and I would like to hear from some of you with regard to all these switches, all of these events, if you will, have, almost of them have end points except for hospitalization and unexplained and those are the ones where they go, they come back and then they do the catch-up. And depending on whether those services are

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in the bundle or out of the bundle creates some weird incentives. And, I think we need to explore that a little bit further.

For example, if we pay a per diem rate, we're going to penalize those people who actually have patients who are frequently hospitalized; therefore, they may be less likely to want to care for them and there would be some type of cherrypicking in that regard. So, we may need to make some type of adjustment or consideration or accounting for those particular issues so that those facilities don't have that, can maybe do it through case-mix, I don't know, but there needs to be some type of consideration given.

DR. RUBIN: Well, more likely, though, the converse is true, which is if you pay people for a month, patient's in the hospital, there's sort of a tradeoff between not expending the resources for the extra treatment versus having to play catchup for the, what are now separately billables that don't appear that they get use utilized in the hospital as much, so I think those are --

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MR. AUGUSTINE: Per diem or not, right? I mean if you per diem you're taking away the days you're in the hospital.

DR. RUBIN: Well, the point is you can't linearly prorate if you are doing it on a monthly basis, and that would be, I think you can take that out.

DR. HIRTH: One approach might be to have to prorate the composition rate costs for the time they're away in the hospital but not prorate the part of the bundle that's going to pay for the things that are being added to it now.

DR. RUBIN: Sure. I mean, there are a lot

of approaches. That's what we're kind of looking at you to see what the data can give us or what we need in terms of the quality of the data. And I think the other piece is to the degree that you can, also that you can tease it out whether there are issues related to more frequent but shorter dialysis in terms of the positive things that come out of it. I know that there have been a lot of quasi-anecdotal stuff in the

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literature in that regard. Dr. Eggers is running a, one day will be running a demo in that regard but he might have some information that would be helpful. Did I see your hand?

DR. LAZARUS: I just, I don't see it in here and it's probably not appropriate under the unit of time but are you going to discuss inclusion of vascular access; are we going to have a discussion on that?

DR. RUBIN: Yeah, that's actually at our second meeting, I think, we're looking at that. Okay. This is a little bit interesting. We're going to I think it's designed as a preview or a peak at case-mix adjustments. If we could go through the, to the next slide. Could you hit the next? Thanks. So, I guess the crew didn't quite get to that slide.

DR. WOLFE: I think that --

DR. RUBIN: All right. Well, let me, let me summarize from my memory. And I think basically the point was made by those people who talked about case-mix adjustments, that they needed to be good.

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They needed to be clinically relevant. Although nobody was impolite enough to be explicit, we ought to acknowledge that 800-pound gorilla that's in the room, which is not too many people were overwhelmed with the proposed case-mix adjusters in either the proposed rule or the final rule. And, so, I think -- and this is not news to you, I know.

So, I think that there are issues that concern people regarding the data, how the data that we do have might differ from the questions that were asked of you and CMS as it relates to the case-mix adjusters to the composite rate, and, how that, how that might, how we might go forward in this demonstration with either new or newly analyzed information that would give the committee confidence in our ability to

appropriately case-mix adjust.
DR. WOLFE: I think it is important to clarify just in case there are any residual concerns about this. The case-mix adjustment made for the composite rate was limited by the available data. We don't know what kind of services are provided

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differentially to different patients under the composite rate system because it has been paid on a flat basis.

What we could, the only data we had available there was from the cost reports which showed how many resources the facilities self-reported in this, we know, limited data system to report costs. And, based upon that we could see if those costs were associated with differences in average patient mix. Now, given those limitations and given what was done for the basic case-mix, and it was a basic case-mix with the intent of continuing to work on that, what we're talking about here is rolling in separately billable services.

And, you have seen a lot of information here. We know very, very accurately or much more accurately what separately billable services are provided patient by patient, month by month, moment by moment. We know whether they're associated with hospitalizations during the month. We know what kind of patients they are directly being given to. So, we

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will have much more information about which kinds of patients require more services amongst these that we're considering right now, EPO, Iron, Vitamin D and the lab services and other injectables. So, the ability to case-mix will be entirely different for this component of the bundle, in that we will be able to see patient by patient what kinds of patients require more services.

So, I think that whatever concerns might have might be in people's minds about that first case-mix adjustment, many of them don't carry over here and I think that you should think instead about what are the opportunities to come up with an appropriate case-mix adjustment based upon the data that we do have. And I will say that while we have much more data available, that's both a blessing and a complication. Because, they're then in my mind one of the important

things for us to sort out is the extent to which we case-mix adjust for what I will call or try and characterize as basic fundamental patient condition, that is, their fundamental medical status versus the way they are responding to treatment and versus their compliance.

To the extent that both compliance and response to treatment are the consequence of what the facility does as opposed to what the patient brings to the facility, then perhaps it's ambiguous about whether you should adjust for that. Serial updates of patient status, I think it's very clear that we don't want to rely upon the patient condition for five years ago when they first started dialysis but at the same time let me go to the other extreme.

Suppose we use hospitalization last month as a measure of their comorbidity for this month, then the facilities that have high hospitalization rates would presumably be paid more because they have sicker patients. Is that a good incentive? The alignment of incentives becomes more problematic as you bring more and more proximate patient condition into the adjustment for the payment system.

So, although we have more data, that doesn't mean it's going to be an easy problem. I think we will be able to come up with a better case-mix adjuster without any doubt but there will still be real important decisions about what is the appropriate level of case-mix adjustment. I think that may be partly what Paul was referring to although it goes beyond there. So, I do want to lay to rest the question of the data source. It is a different data source for the separately billables and it doesn't have the problems that we have of the data source before the limitations. At the same time, I think we'll have a different kind of problem to resolve and ones which are very complicated.

MR. AUGUSTINE: Then being complicated, let's err on the side as best as we can to let the community be able to reproduce many of the results, at least. We may not be able to share everything but at least they should be able to get somewhat close. And I do want to take you off the hook, and look, you know, because of the fact that KECC was receiving direction

from CMS and we were administering it as we saw fit under the law. So decisions that were made were CMS

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decisions. One thing from developing payment systems in the past in the private sector is they tend to work best when they were iterative. You don't get it right with just one crack.

And so we received a significant amount of comments on the proposed rule. And myself and many others from the agency have read every single one of them and looked at the data and tried to incorporate all that we could in there and make it as fair as possible. And we expected this will not be the last iteration and we will continue. That's one reason why we're excited about being here today. It's better to work on something going forward together in that fashion having access to the analytical resources that we have as opposed to the rulemaking process where things are much more conservative.

DR. RUBIN: If I understood the thrust of your comment -- and jump in if I'm misstating it -- you have much more robust data on the separately billable piece but because for the composite rate the data sources that you use are the same ones that you've used

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before, that's really not going to change in terms of your ability to deal with that.

And, so, I guess the question is, and this is, as I said earlier, we ought to acknowledge the data deficiencies, not that it's your fault or anybody's else's, just that we don't have what we might need. I mean, it would be great if we could do time and motion studies that are patient-specific in dialysis units, perhaps. That ain't going to happen between now and January '06 that I've seen.

But, my point here is, what do you think, will you be able to tell a relative contribution in terms of explanatory variables for both the case-mix, the composite rate component versus the separately billable component and then some degree as some of the work we did for the RPA, looking at patient size or the number of patients you need for these random variations to be somewhat mitigated.

DR. WOLFE: Bob, you bring up very good points that we do have a separate data source for the separately billable and for the composite rate. Our

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current thinking is that we would actually develop those separately, recognizing limitations of the composite rate bundling essentially, and then add them together to come up with an overall payment. We don't know if that's what CMS would find attractive in terms of implementation or not. That is certainly one of the proposals that we will be making to CMS. And it will also be very clear in both of those components the extent to which there are different kinds of impacts on different kinds of facilities and the extent to which we can explain the amount of variation at the facility level.

For the patient level we will only be able to do that on the separately billable side. And, we will certainly have much less predictive power at the patient level than we do at the facility level, because of the averaging effect at the facility level. And actually that is an important thing to keep in mind, the inability to predict exactly what happens patient by patient isn't as important as getting it right on average at the facility because on average the facility

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is what drives the economic viability of the facility delivering the services.

I don't know if it is worthwhile to spend just a little bit of time, I don't know how familiar people are with the basic case-mix adjustment to the composite rate system. It has three components. They're shown on the slide here. They're not in your handout. If you want to look at it, there is an age component, which is shown graphically there as multipliers of the basic composite rate and there are different multipliers for different age groups. You can see that the multiplier goes up for the older ages, above age 60, recognizing that those folks cost more per session.

And there's also a body surface area or body size component which is the major effect within this case-mix adjustment. Larger patients cost more, and this is consistent with the actual practice of up to four hours of dialysis versus three hours of dialysis for the small versus the larger patients, and also the very different kinds of dialyzers that are

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used for the larger patients compared to the smaller

patients.
DR. RUBIN: Excuse me.
DR. WOLFE: So this is a well understood effect. The body mass index is the third component representing frail patients at the low end. A cutoff of 18 and a half was used. This is consistent with the standard definitions of malnourished and it was also based upon the data that this was the cutoff that appeared to be the most predictive of costs based upon the basic case-mix.
So, nearly all of the components here have a lot of face validity and agree with well with the general understanding of what drives costs. I believe, at least this is the feed back that I've gotten. There has been a concern expressed about the 18 to 44-year-old multiplier, that it seems large to many people. I will say that it is what the data showed and to the extent that there are plausible explanations for it may be that people simply haven't thought about some of those explanations.

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For example, those patients do have a much higher fraction with AIDS. I think it's close to 8 percent. They have a much higher fraction with drug dependence, about 10 or 11 percent, I believe. They're twice as likely, as older patients, to be skipping sessions, which means that you miss the opportunity of getting the payments for them by filling those chairs.
So, there are reasons why those costs are higher. I don't know the extent to which those actually explain why it is as high as it is but there is medical plausibility to much of the relationship that we see here. So, Bob has pointed out some of the concerns raised about this but at the same time there is a lot of plausibility to it. It will really makes sense to a large extent except for one or two concerns that people have and many of those, and even those may be explainable and understandable.
DR. RUBIN: I was afraid what I just saw happen was going to happen. We only have about seven more minutes for this session and I really want to talk about what's going forward but clearly some people have

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an urge to say something in response to what you said. So, well, why don't we just, the first people that pressed the buzzer I think were Paul Eggers, Mike

Lazarus and Bill Owen and then why don't we move on.

DR. EGGERS: Yeah, I'll be very brief. I'm assuming that given all the work that went into this that in a bundled payment you pretty much live with this, this adjustment for that part, the composite rate. I mean, that would be my assumption and that the additional amount would be, as you point out, with individual level data and stuff you would be able to adjust on that.

Again thinking again outside of the box a little bit here, the effect of covariates might differ depending on the, what do we call it, the length of time that we're looking at, so that my hypothesis would be that age, for instance, wouldn't affect much of a single session but it might affect over a week or a month or something like that. So, just kind of think about that a little bit in terms of modelling. You might have two or three different models depending on

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one for a per session treatment, one for a week and one for a month.

MR. AUGUSTINE: Well, all this could change. I mean, even if we go to an expanded bundle these numbers would change because there may be an interaction between EPO and some of these composite level data as well. For example, let's say that African-American males tend to be younger and tend to be the ones that skip -- I don't know if that's true but just as an example -- there could be some correlation there, that would make these numbers change in an expanded bundle environment. And that's something we need to be aware of.

The good news is, is that, as Bob stated earlier, when we have patient level date that's much more predictive we will explain much more variation and the variation that would be explained by this additional information would overwhelm the information in many regards because it's not near as predictive information from the composite rate adjustment.

DR. LAZARUS: Could you put the slide back

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up, Bob? I don't think there's a clinician in this room that will look at that chart and believe the 69-year-old costs that much less to care for than an 18 to 44-year-old. I mean, I just have real problems as a clinician taking care of patients for 35 years

believing that despite the fact that there might be 2 percent of patients with AIDS and some --

DR. WOLFE: 8 percent.

DR. LAZARUS: No, not in my population. I don't know where you got that number from but I can tell you mine is 2 percent. So I have to disagree with the number. But it's a small population, but the outcome, and better people, by the way, get better outcomes. They clearly are better. There have been numerous studies that have shown that people do better. They're less -- to take care of. The end result of your case-mix adjustment is shown in the example that I keep bringing up is that an 18-year-old male gets reimbursed $170 and an 82-year-old malnourished woman gets $140.

But if you take a 69-year-old woman with a

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body mass index of 19, it goes down to $106, with the model. That will drive behavior in the wrong direction for patients, for CMS, and for everybody. Facilities will not take 69-year-old malnourished ladies of which they get $106 when they can get an 18-year-old male, whether he misses or not, they get $170. It will drive behavior in the wrong direction. Well, you may not find it but we'll go out and look for it. What will happen is and maybe if that's what you want to happen we'll stop taking the care of the frail elderly and I don't think that's what anybody wants but this model will drive that behavior.

DR. RUBIN: Bill?

DR. OWEN: I would just like to underscore what Bob had raised earlier and is for me a bit of a cautionary note, and, my unease about case-mix adjustment as schizophrenic as I might sound albeit I embrace it is the potential to compensate for an absence of responsiveness, which is to say I've got something that is manageable and because I have shown an association to cost, I make an assumption of

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causality, almost protopathic bias and then I compensate the provider for that and the incentive is lost for the provider to fix it.

So, for example, I say, well, I've got an older -- well, we have the chart down but I've got an older person and they're diabetic and they have poor vasculature and they're more likely to have a graft and

their costs are going to be higher so I'm going to pay them more; therefore, I've lost the incentive, the drive, to go back and fix it. And I have seen healthcare systems outside of the U.S. where they tried to do case-mix adjustment and the cautionary note on that is that they reimbursed inadvertently not very aggressive interventions to improve things.

MR. AUGUSTINE: Let me, that's one of the major cruxes of case-mix, what's a priori and what happens during the session. And I do know there's, that there are some proposals to the change the information we get from hospitals to include whether or not something happened during the stay or not -- I read about that recently -- which would help us in our

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case-mix activities. But those points are quite valid.

DR. RUBIN: Would, having said what you said, do you have a proposal to the KECC people as to how to deal with the issue?

DR. OWEN: You know, unencumbered by any knowledge I would say as a first point to try to categorize what their profiling is being constitutive to the patient, things that I have absolutely no control over versus those that arguably are things that are manageable. So, if somebody's got HIV, I can't change that. If somebody is skinny and malnourished, I'm going to argue that maybe that is something that can be adjusted. I can't change someone's age.

MR. AUGUSTINE: But you may not control it completely but you can mitigate through proper management an MI patient or if you were managing the patient.

DR. OWEN: If I'm managing the patient, yes, but, you know, you know, things that you know, that God and my parents gave me arguably I can't change too much but things that are related to, that might be

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influenced by process of care, I got a lot of concern about doing case-mix adjustment on them.

MR. AUGUSTINE: Well, what would you say, all right, let me, let's say you case-mix adjust for major comorbidities that affect these beneficiaries, what would be your reaction to that?

DR. OWEN: You know, I got some unease about it. You know, let me give you by example and that is, you know, the older patient who's had an MI

and has AFCHF clearly costs more so I'm going to pay him more. Well, you know, maybe I am in doing that driving away the initiative, the incentive, the innovation to try more aggressive things to manage that congestive heart failure.

You know, maybe I'm paying you to not think about using a beta blocker in that person. I don't know. It's a very difficult, it's obviously a difficult problem but I can see a circumstance where we say we've got these associations and we can identify a chain of logic to account for why they cost more so let's go ahead and pay for it. And, in doing so, we've

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lost the incentive to have the aggressive initiative to try to manage it. As Paul and I were discussing earlier, in health service you get one check. You manage it. You make it work. In international health systems you get one check; you make it work.

MR. AUGUSTINE: Right.

DR. OWEN: And, you know, but that's a kind of an extreme version but I'm saying, you know, maybe we need to be, have a little caution about how much we allow case-mix adjustment to drive what we pay for.

DR. RUBIN: Well, just to again, let's come back to the major point here, everything you say would be a lot more acceptable to me if what we were doing was the demonstration that's about to get underway, which is a capitated, I'm responsible for every single cost and I have, I do get one check and I can divvy it out. That's not what this is. This is facility composite rate separately billable drugs and maybe some other things that we want to throw into the mix depending on future deliberations. It's not Jane falls down, breaks her arm and we got to take care of it.

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DR. OWEN: Right.

DR. RUBIN: And so, it's a very, very different question. And, I think we're, there are a couple of issues. Number one, I completely agree with Mike Lazarus and in fact I believe I was one of the people that called him when I read the thing in the Federal Register, that this, you know, this just didn't make any sense.

DR. OWEN: You did a logic check.

DR. RUBIN: But the problem is it's not, it's not necessarily seen as a problem in terms of the

data, it's the correct data isn't available. And, so, we could talk about the bureaucratic process and all of that and I have been there and sometimes you kind of make do but the point here is we have an opportunity to say what we want to put in, we ought to identify what we want to leave out and we ought to tag it and say, yeah, the data is terrible but we kind of think that this is something we want to do and it's better than doing nothing or whatever.

But, we shouldn't place too great a burden

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on the information system on the one hand but on the other hand we need to be honest about what the heck we're measuring. And so what I'm going to be a big proponent of going forward is transparency, and let's be clear about what our assumptions are, and then we can see what our case for risk is and, you know, as I've said before, we don't want to throw a party that nobody comes to.

MR. AUGUSTINE: Bill, one following comment after that wonderful discussion, is that with case-mix you run so much risk, if you do it, if you don't do it, especially in an expanded bundle environment, you're going to have --

DR. OWEN: Nobody will show up.

MR. AUGUSTINE: -- serious cherrypicking.

DR. OWEN: Uh-huh.

MR. AUGUSTINE: So, it's one of those issues where the good outweighs the bad. And you try to guard against those type of utilization patterns with, for example, pay-for-performance and other means. It's a balancing act. There is no perfect payment

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system. There are a lot of things that you try to weigh against the middle and the middle being the patient care focus, and that's really kind of what we continue to talk about.

DR. RUBIN: Well, try as we might we thought we would get all of the people in the public to leave because they wouldn't find this stimulating enough but that's off the record.

DR. EGGERS: They looked outside and it was raining so this was just as good.

DR. RUBIN: And CMS made the mistake of having coffee available but in any event we have reached the time in the agenda that those people who

have patiently been listening to the folks over here say things now can unburden themselves with what they're been keeping pent up.

I must say that we twice tried to figure out how much time to allocate by asking people to identify themselves in advance. That failed, so, what we're going to do is, this is going to be, this is people's opportunity. If nobody steps up to the mike,

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we're going to forge on and my guess is that no one in this room will be unhappy if we finish early.

So, is there anybody that would like to make a comment regarding, aside from the people on the committee, that would like to make a comment? I would like for you to identify yourself because we are keeping minutes and keep your comment to five minutes or less.

DR. CRONIN: I have a comment and question. My name is Dick Cronin and I am the medical director of the American Renal Association. I have one philosophic comment which has been danced around a little bit here today. And that's that you have to be very careful that in bundling payment you do not fragment the patient and make their lives more difficult. And that's a very easy thing to do. And I have been an everyday nephrologist as well and they live hard lives and we can't make them harder. I had a question for Dr. Wolf. Do you have the ability to take the MAC data and to correlate that with comorbidities and ICDM-9 codes or ICD-9 codes?

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DR. WOLFE: We do for separately billable services.

DR. CRONIN: Uh-huh. Okay.

DR. WOLFE: And we can do that both based upon conditions of the patient at the time of initiation of dialysis and conditions that occurred during hospitalizations and diagnoses that are made in the doctor's office.

DR. CRONIN: That seems to me that might be a valuable tool.

DR. WOLFE: Absolutely. Thank you.

DR. RUBIN: Anybody else care to make a comment or ask a question? Dr. Pereira?

DR. PEREIRA: Brian Pereira. I just wanted to bring up an issue that Bill Owen raised with me

today that I think very important for the Committee to address. The question is, are we trying to manage ESRD in the patient or the patient with ESRD. And oftentimes we talk about the clinical practice guidelines. Well, the National Kidney Foundation KDOQI initially dealt with issues which were largely specific

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for dialysis such as vascular access, dialysis adequacy and so on, anemia being one which wasn't.

The newer guidelines have been now looking at issues such as how do you manage lipid abnormalities, how do you manage diabetes, blood pressure and so on. So, I think there is a wealth of information that is coming into the domain of kidney disease wherein we are looking at how do we treat the patient rather than just treat ESRD.

So, as we go forward I think the Committee needs to answer this first. This the first fork in the road. The next fork in the road is, are we going to bundle it based on modality or not because that's where we start providing incentives, financial incentives to choose a modality if you have a one size fits all.

The third step or the fork in the road would be what should be and should not be included in the bundle and you have discussed that quite elegantly. After that you go to what's the unit of payment and then you start looking at case-mix and other adjusters and then further down the road whether you're going to

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do it at the unit level or the patient level, look at the issues that Mike Lazarus brought up about cherrypicking of patients.

And then finally as you start closing the loop the issue of quality of care, a feedback loop and what is the frequency of updates. So this is just a view from the bleachers as to how the roadmap for the discussion could be structured as we go down this path.

MR. AUGUSTINE: Thank you, Dr. Pereira.

DR. RUBIN: Anyone, anyone else? Okay. This is your last chance. Fine. If we could -- could you just keep circling here? Here we go. For our next meeting, what we are going to do is look at the three things we talked about today. We will get feedback from the University of Michigan for what they thought they heard us asking for. We will get feedback from CMS staff who have been interspersed around the room

and hopefully diligently taking notes and they'll give us some feedback about what they think they heard us asking for. We'll amalgamate those two lists, circulate them to the Committee to make sure that the

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Committee thinks that that's what it was we were asking for. And, hopefully all of that will be done prior to our next meeting.

In addition, we're going to be discussing case-mix adjustment, issues for outliers, and begin a discussion on quality incentives and pay-for-performance. I would urge everybody on the Committee that has things that they want to make sure we present analysis and/or data on regarding those issues to contact, use the contact numbers that Brady Augustine mentioned early at the outset of this presentation or, if you're like me, you're a little challenged in that regard.

We all got e-mails from either Pam Kelly or Heather Grimsley and just pull it out and hit the reply button and I'm sure that they will make sure it gets to the right people. And they just cringed in their seats because I'm not sure that was on the program but that's okay.

The third meeting will be to review the payment system design that we come up with at the

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second meeting. We want to talk a little bit about the update and what it should include, to some degree the methodology, although my guess is that the methodologies are reasonably well-trodden by Nancy and her colleagues, since they have done this for every other PPS system.

And then we want to look at the demonstration design and the plan. And, that will include the quality incentives and pay-for-performance. We will send e-mails out to schedule. My preference would be to schedule both the second and the third meeting in the next couple of weeks since most of us have calendars that are terrible and the sooner we can do that, the better.

When we, when I talked with Brady earlier in the month, I think what we're looking for is a second meeting sometime end of March, beginning of April, and a third meeting sometime in the second part of May. And, so, we'll send you a preference sheet and

hopefully we can get everybody here. I don't have anything else. Do you.

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MR. AUGUSTINE: The only thing I have -- Paul, go ahead and I'll finish off.

DR. EGGERS: Well, as usual I'm sort of out of sync with we were actually talking about but just a comment to Bob Wolf is I have been thinking quite a bit about this business of using the bill data to identify adverse events, you know, that we have been characterizing the population and, you know, if it's too close to the time then it's, you know, adverse incentives. You might consider taking the approach that's very, very similar or maybe even exactly the same as the Medicare Plus Choice in which you use the prior year and characterize the patient and that data may already be available and accessible to you on the ERSD population.

DR. WOLFE: Thank you. We have done that kind of analysis also.

DR. EGGERS: Okay.

DR. WOLFE: And I think that that's a very good option. It is more complicated but certainly we already have the model for it.

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DR. EGGERS: Well, but it also is, you know, there is also sort of innocence by association or guilt by association by using something that people know from another venue.

DR. WOLFE: Thank you.

MR. AUGUSTINE: All right. Well, let me follow with one comment. I don't want this to be the last of our discussions. I don't know how it works with -- in case someone on the board asks someone else on the board a question.

MR. BACHOFER: They can talk amongst themselves.

MR. AUGUSTINE: So --

DR. WOLFE: It's not like a jury.

MS. GREENSPAN: A jury.

MR. AUGUSTINE: So, I mean, if people have questions and would like to discuss items, all I ask is that verbally we would include the entire board on any of this, on any e-mails even though most, some of us it would be a little extra bit of a hassle just for the sense of transparency I would like to err on the side

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of caution in that regard. As well, the last item of the day is, like I discussed earlier, we at CMS are always interested in continued quality improvement. And we have included an evaluation form. If there are ways that this meeting could be improved, please feel free to let us know and you can leave it with myself or with Linda.

MS. GRIMSLEY: Mine's blue.

MR. AUGUSTINE: Oh, blue? Mine's white. Yours are blue.

DR. RUBIN: That's because we want to know what you said.

MR. AUGUSTINE: Oh. So much for anonymous surveys, right? Just fill them out, leave them with myself or Linda Magno or Bob and we'll make sure that they get addressed. And that's it. Anyone else? Oh, parking.

MS. MAGNO: If you self-parked here, stop at the desk on the way out and pick up a card from the meeting. It's just an organizer that discounts the parking. That's it. It looks like this.

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MR. AUGUSTINE: All right. Looks like we are adjourned.

(Meeting concluded at 4:31 p.m.)

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State of Maryland

Baltimore County, to wit:

I, ROBERT A. SHOCKET, a Notary Public of the State of Maryland, County of Baltimore, do hereby certify that the within-named proceedings personally took place before me at the time and place herein set out.

I further certify that the proceedings were recorded stenographically by me and this transcript is a true record of the proceedings.

I further certify that I am not of counsel to any of the parties, nor in any way interested in the outcome of this action.

As witness my hand and notarial seal this 1st day of March, 2005.

_____

Robert A. Shocket,
Notary Public

My Commission Expires:
November 1, 2006