# MEDICARE PAYMENT ADVISORY COMMISSION

## PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Thursday, October 7, 2010
9:45 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
ROBERT BERENSON, MD, FACP, Vice Chair
SCOTT ARMSTRONG, MBA
KATHERINE BAICKER, PhD
MITRA BEHROOZI, JD
KAREN R. BORMAN, MD
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THOMAS M. DEAN, MD
JENNIE CHIN HANSEN, RN, MSN, FAAN
NANCY M. KANE, DBA
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GEORGE N. MILLER, JR., MHSA
MARY NAYLOR, PhD, RN, FAAN
BRUCE STUART, PhD
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [9:45 a.m.]

MR. HACKBARTH: Would you take your seats, please? Okay. Welcome to our guests and, I am sorry, it looks like we may not have enough seats. Can you see any vacancies here, Mark?

DR. MARK MILLER: I'm not seeing any.

MR. HACKBARTH: We begin this month's meeting with a presentation and discussion on shared savings program for ACOs, and then we will have a report on a panel about identifying high- and low-value services before lunch.

For those of you who are in the audience who are new to MedPAC meetings, we will conclude each session with a brief public comment period, so we'll have one of those right before lunch and then also at the end of the day. When we get to that point, I will talk about the ground rules for the public comment period.

So let's turn to ACOs. David, Jeff, who's leading the way? David?

MR. GLASS: I'll start off. Last months we briefly reviewed the legislation on a new Medicare program for accountable care organizations which starts in 2012. You discussed several issues relating to the program and the

regulations CMS will have to write to put the program into practice. Today we will summarize your comments from last month and expand on some of the points on which you wanted more information.

So, to quickly review, ACOs are health care organizations formed around a core group of primary care providers serving at least 5,000 fee-for-service Medicare beneficiaries. Those providers could be, for example, physicians, nurse practitioners, or physician assistants. While an ACO must have primary care providers, having a hospital or specialist in the ACO is optional.

An ACO must also show CMS that it has the capabilities listed on the slide there. CMS will have to make a judgment call as to whether the ACO meets those criteria. And remember, ACO patients are still free to use providers outside of the ACO. And if they choose to go to a specialist or hospital outside of the ACO, the ACO remains responsible for the spending.

With that definition in mind, we want to build on last month's discussion of the following issues, the first four of which CMS will have to address in regulation.

The first issue is informing patients of their

primary care provider's decision to join an ACO and of the patient's assignment to that ACO.

Second is about what quality metrics in general should be used to determine if an ACO is meeting quality benchmarks.

Third is about minimum size and how the consideration of how random variation in cost and quality metrics influences the question of minimum size.

And the fourth issue is about how benchmarks should be influenced by the historical level of spending in an ACO.

Finally, we also want to see if we can define in broad terms a two-sided risk model. Some ACOs may find the high thresholds that will be required before they can qualify for a bonus too onerous in the bonus-only model. Because the high thresholds may discourage participation, giving ACOs the choice of an alternative model may be helpful. In addition, the two-sided risk model may have stronger incentives for savings than the bonus-only model.

Before we discuss the first issue of informing the beneficiary, let's briefly review how assignment of patients to ACOs works.

The Secretary is to determine an appropriate method to assign beneficiaries to ACOs based on the utilization of primary care services provided by an ACO professional. That method will have to be specified in regulation. A key point is that beneficiaries do not enroll; they are assigned to a ACO by CMS based on which primary care provider they use.

First, the primary care provider has to choose to be in an ACO. and then CMS assigns patients to the provider and thus to the ACO. If we want the patient to know in advance that their primary care provider is in an ACO, then assignment has to be prospective as opposed to retrospective. For example, under prospective assignment, to evaluate the ACO on 2012 performance, CMS would have to look at 2010 claims to assign patients.

Last month a number of you said that beneficiaries should be informed when their primary care provider has joined an ACO and when they have been assigned to that provider. In addition, we think you said the beneficiary should be allowed to opt out of that assignment. Informing the beneficiary would fulfill the beneficiary's primary right to be informed that their provider now has a new set

of incentives. It may help avoid the equivalent of the managed care backlash that resulted when patients were suddenly put in a new situation not necessarily of their own choosing.

On the positive side, informing the beneficiary could help get the patient engaged in his own care management, which many deem to be necessary to the success of an ACO. Shared decisionmaking could be an example of patient engagement.

We also heard that there should be an opt-out option for the beneficiary. Opting out means either the patient could choose to switch to a different provider who is not in an ACO, and it is clear from the legislation that that's allowed. Or the patient could stay with her provider but her data does not count in the ACO's evaluation. This would be an new definition of opt out.

We also think, many thought, that the policy should be designed so that opting out has to be a conscious choice of the patient. The default option is if you are assigned to an ACO and do nothing, you stay in the ACO. This draws on the literature that says what is set as a default is important. For example, 94 percent accept auto

assignment into Part B, and CMS uses auto enrollment for Part D LIS assignment.

The second issue is quality and how it should be measured and assessed. Several of you said there should be a small set of quality metrics that could be synchronized over all payers, and that would reflect the outcomes the ACO program is designed to achieve. Candidates mentioned included emergency department use, potentially preventable admission rates, in-hospital mortality rates, and possibly patient safety measures, readmission rates, and patient satisfaction and health status.

The measures chosen will be important not only as indicators of the quality expected, but also because they may indirectly affect which kinds of organizations choose to become ACOs. For example, including hospital safety measures could encourage ACOs to include hospitals or hospitalists. The idea seemed to be to keep to a small set of measures and not overdesign the solution. Moreover, those measures should work across all payers, not just Medicare. This will help reduce the burden on the ACOs and provide more impetus to the measures used. It also increases the number of cases in the calculations, thus

improving their statistical reliability.

Jeff will now take us through the remaining issue.

DR. STENSLAND: You may recall this slide from last time, and there are just a couple key points to remember in this slide.

First is that random variation is large for small ACOs. As we see from the first column in this slide, roughly 10 percent of ACOs with 5,000 beneficiaries would have cost growth 3.6 percent below the national average even if they did nothing, and this significant random variation necessitates large thresholds to prevent paying bonuses based on random variation.

We should also recall that, as Corrie pointed out last month, this is just a random variation in individual ACOs compared to the national average. This does not include surprises that could occur in the national average growth rate of spending. Therefore, this should just be seen as a lower bound in the overall variation that could drive random bonuses.

And, finally, you may ask, While we show the 10th percentile and the 90th percentile, what would, say, be the 25th percentile for pools of 5,000 beneficiaries? The

answer is about 2 percent. So if there was a 2-percent threshold, about a quarter of all 5,000 member ACOs could receive bonuses even if they didn't change their practice patterns at all.

So what are the implications of having small ACOs in terms of measuring efficiency and managing care?

The first implication, as we just discussed, is the need for large thresholds to prevent random bonuses.

Second, there was also some concern that small ACOs of eight or ten primary care physicians may have medical home type capability to manage care, but they may not have the abilities we want in an ACO to track and manage all areas of care, including inpatient, outpatient, tertiary care, and post-acute care. So the issues with small ACOs are not just the random variation.

Finally, how could CMS reduce the odds of paying bonuses for random variation? One method brought up would be for CMS to accumulate data for three years, and then if CMS found the savings to be persistent, then they could pay out the bonus. While that could reduce random bonuses, we would still have that problem about some of the smallest ACOs and their difficulty fully managing care.

Another area we discussed last month is setting benchmarks. As you recall, in the June 2009 MedPAC report on ACOs, we discussed two options for setting benchmarks. They both set the targets for Medicare spending based on historical spending levels, but there are some differences.

The first model has a common spending growth amount across the nation, say $500 per capita. The result is that the allowed level of spending for historically efficient ACOs would still be significantly lower than the allowed level of spending for historically inefficient ACOs.

The second alternative model is to have historically low-cost ACOs be allowed to have slightly larger amounts in the level of growth in spending. So let's show this in detail to make this a little clearer.

This here is the first alternative, the base model. As a reminder, the PPACA sets the absolute growth amount, a fixed dollar increase in spending per capita for each ACO in the country. And it is set at the projected growth in fee-for-service spending for A&B services.

For example, in this case, assume the national average costs per beneficiary had been $10,000 per beneficiary per year, and CMS projects spending growth of

$500 per beneficiary. ACOs could then be given an average of $500 growth allowance each, or a 5-percent resulting growth allowance, as you see in the bottom row of the first column.

If we go to the second column, we see for a low-cost ACO that historically had $7,000 in Medicare spending per beneficiary, their spending target would be $7,500, meaning they would have to keep their spending growth below a 6.3-percent increase in order to get a bonus. In contrast, a high-spending ACO with a historic level of spending of $12,000 per year would still get that $500 target spending growth, and that would be equivalent to a 4.2-percent increase in their spending in order to achieve the bonus.

But, nevertheless, the main point here is to note that the historically high-spending ACO would still have a much higher target -- namely, the $12,500 -- than the historically low-spending ACO with the $7,500 target.

The second model is to address that issue. In this method, historically low-spending ACOs get the benefit of a higher target growth amount. In the second column, we show that in this model the ACO that had spent $7,000 per

person would be given a larger growth allowance of, say, $600, for example. Its target spending would then be $7,600, and this is just illustrative. There is no firm figures on how this would work. And you can think of this higher growth target as a reward for past good behavior.

The result of this method is it would slowly close the gap in target spending between historically low-spending ACOs and historically high-spending ACOs.

One concern from last month was that lower spending ACOs that meet their targets will see lower targets due to improving their spending performance, and this approach may allay that concern to some extent.

In addition, I want to remind you that the law sets the growth targets and the spending targets for at least three years into the future. So it says we'll look at your historical spending and then we'll set up a plan for the next three years. They call it some sort of an agreement for the next three years. So the growth performance, if they have really good spending constraint in year one, it won't immediately reduce their growth targets for year two. So that should also allay some of that concern about good behavior leading to lower growth targets.

All right. So everything we've talked about so far -- informing the beneficiary, setting the quality targets, setting spending targets -- all those things could apply to the bonus-only or to a two-sided risk model. And the next question is, Why should we go beyond just a bonus-only model?

The key points from this slide are:

First, that the bonus-only model has weak incentives to induce providers to reduce their own fee-for-service revenue, and we talked about that last month. The reason incentives are weak is because there is significant random variation in spending, and random variation forces CMS to have significant thresholds to reduce payments, to prevent payments from being made based on random variation.

So then if there is this issue with the bonus-only model, what is the alternative? Last month we talked about a two-sided risk model. This would have upside risks and downside risks. The idea is that providers in the ACO would share in the first dollar of savings, but they would also share in the first dollar of overspending.

Providers may be willing to take the downside risk if CMS gave them three things in return: first, they could

benefit by getting a share in the first dollar of savings -- in other words, no thresholds; second, CMS could provide them some downside protection if the form of risk corridors so they wouldn't face real large risks of decline in revenue; and, third, CMS could potentially waive some regulations such as the regulations on gainsharing.

Now, patients may also be attracted to this model if providers were given the ability to waive some cost sharing on certain cost-effective care. Now, because in this two-sided risk model the ACO would face some downside risk if spending grew up rapidly, CMS may be less concerned about providers choosing to waive cost sharing in order to increase volumes of services. Hence, in the two-sided risk model, waiving some cost sharing may make more sense than it does in the pure fee-for-service model or the bonus-only ACO model.

Now, the two-sided risk model we show here could be seen somewhere in the middle of the risk continuum. On the one side, you would have the bonus-only model with essentially no risk. On the other side, you would have the full capitation model where you're at risk for all of the spending. And this two-sided risk model gets you somewhere

in the middle.

Now, there are other models that get you somewhere in the middle of this level of risk that were discussed in the legislation and have been discussed elsewhere. These would be partial capitation models where you're capitated for a part of the overall spending or you're capitated for a part of the type of services provided, maybe for physician services.

Now, there is a difficulty implementing these partial capitation models in the ACO context, and the reason is that in the ACO context, remember one of the fundamental principles is that the patient can go for care wherever they want. They do not have to stay in the ACO. So at the beginning of the year, when you would have to make the partial capitation payment, you wouldn't actually know how much of the patient's care is going to be provided by that ACO. They may decide to go somewhere else for care. And even for the whole group of patients, you wouldn't know exactly how much would be provided within the ACO.

So because you're not sure how much of the care the ACO will be providing, it's very difficult up front to decide how much of a capitated payment they should get. And

for that reason, the two-sided risk model is much easier to implement and to track than the partial capitation model, at least in the ACO context.

So just to recap, last month and this month we've had some discussions, first about how Commerce Department should inform the beneficiary, get the beneficiary engaged in their care, and give the beneficiary some choice with respect to the ACO, especially -- we don't want the beneficiary at any point to be surprised that they're in an ACO.

Second, we talked about setting a small set of quality metrics.

Third, we talked about how small ACOs face some limitations and that large thresholds are necessary for these small ACOs to prevent bonuses paid on random variation.

And, third, we discussed how benchmarks could be set so that target growth amounts are larger for historically low-spending ACOs and those target growth amounts could be higher for historically -- excuse me, the target growth amounts would be higher for historically low-spending ACOs and the target growth amounts would be lower

for those that have historically spend larger amounts.

And, finally, we talked about how we could give ACOs a choice. They could take the bonus-only model, but that would have high thresholds to prevent those random bonuses. The other choice would be a two-sided risk model, and the two-sided risk model would have stronger incentives to control Medicare spending.

I'll now open it up for discussion.

MR. HACKBARTH: Thank you, Jeff and David.

For the benefit of the audience, let me just emphasize what we're doing here. The purpose of this and our previous conversations is to develop information for a comment letter to CMS. As I think most people in the audience know, CMS is preparing a proposed rule implementing the gainsharing program. So as opposed to what we usually do, have these conversations to produce recommendations for our March or our June report, this is on a different schedule, a somewhat accelerated schedule, and the output will be in the form of a comment letter.

Okay. So let's have our round one clarifying questions for David and Jeff. We will start over here.

DR. CHERNEW: I have a question about Slide 6.

It's the one on synchronize a small set of quality measures. Do you mean a small set of outcome-oriented -- in the stuff you sent us, you used the word "outcome" versus "process." Or do you mean a small set of output? I don't think --

MR. GLASS: I'm sorry. We meant outcome, yes.

MR. HACKBARTH: In the spirit of clarification, Mark just told me I mistakenly said "gainsharing" when I meant to say this is about the shared savings program under the Affordable Care Act.

Other clarifying questions on this side?

DR. BERENSON: Yes, can you put up Slides 2 and 8 simultaneously?

[Laughter.]

DR. BERENSON: It goes through a definition of the ACA's definition of an ACO. Jeff on Slide 8 picked up part of the conversation from last time. I was one of the people emphasizing the fact that we expect an ACO to provide a full continuum of care, full spectrum of care, and a small practice can't do that. But is there anything in the legislation explicitly that says that we expect an ACO to be responsible for the full continuum of care? I understand their target is based on A and B spending, but I've actually

been approached by people who want to set up specialty-specific ACOs, and I've said, well, that's not what an ACO is, or a medical home is not an ACO, because you're not providing the full continuum of care.

Is it implicit or explicit, or neither?

MR. GLASS: Well, I think they're responsible in some sense for care management even though -- improving care management even though they're not responsible for providing the full spectrum of care.

Do you have the specific wording, Jeff?

DR. STENSLAND: There is a series of things that they require the ACO to do, and I think it would depend on your interpretation of those things. You know, you are coordinating care, you are being patient-centered, you're providing an adequate amount of information on the quality of care being provided and care transitions. It's all the stuff that -- I'll get back to you on the exact details, but I think it's open to interpretation of those things of how much you have to be able to do.

DR. BERENSON: But is it your understanding that -- well, I mean, the logic in 8 is correct. I assume that we would like ACOs to, in fact, either directly provide or be

able to be responsible for, through arrangements with others, the full continuum of care. That's the expectation of what an ACO is. Right? Okay.

MR. HACKBARTH: Right.

DR. KANE: Slide 11. You were talking about the growth rate being set for three years forward based on the expected national average rate of growth in A and B services, but that the base -- your base spending wouldn't change? Could you just tell me a little -- I'm not sure I understood that mechanism. Just maybe clarify.

DR. STENSLAND: All right. So there is what they call the agreement period. So there would be an agreement period that has to last for at least three years, and you would look back and say, okay, this is your historical -- this is my understanding of how it would work. You would look back and say here is your historical spending, and so we're going to give this as your base amount that we're going to work from. And then for year one, we'll have some expectation of growth, so this will be your target in year one. In year two, there will be another expectation of growth, so that will be your target in year two. And in year three, there will another expectation of growth, and

that will be your target in year three.

So you're starting from the same historical base amount that started before you formed this three-year agreement, but then you'll have some sort of amount of allowance for growth in each one of those three years in the agreement.

DR. KANE: And then what happens in year four?

DR. STENSLAND: Well, that's not clear what happens in year four, and also they say the agreement is for a minimum of three years, so it's not clear that maybe you could have a longer agreement in place with CMS than the three years.

DR. KANE: Okay. Thanks.

MR. ARMSTRONG: We make the point -- and we talked about this last time -- that a beneficiary size of about 5,000 is small and creates some issues with -- and I agree with that based on my own experience. But the question I would have is: Have we ever done any work that would identify a volume of beneficiaries or a number where it's more stable or more predictable, some of these trends?

DR. STENSLAND: Put up the slide. The bigger the pool, the greater stability there is, as we showed in Slide

7. So this kind of gives you the pool of 10,000 or the pool of 20,000. And even at 20,000, we see at the 10th percentile there's still some bouncing around of 2 percent. It's not as big a concern, but it's still some bouncing around. So I think that would be CMS in the PGP demo, even though they had pools on average of 20,000 people in each of the PGP demos, they still had a threshold of 2 percent.

MR. ARMSTRONG: Okay, I get it.

MR. GEORGE MILLER: So this question comes under what happens if you gave a party and nobody showed up, and that would be what percentage or what number of people who are automatically in the ACO then choose to opt out of the ACO. Is there a number or percentage that then -- I guess it would be at the low end, the 5,000 then would not make them an ACO, and I guess then you could apply that to Slide 12 that Nancy asked that question to. What would happen to the three-year spending if an appreciable number of people were to opt out of an ACO and choose not to be in another one?

DR. STENSLAND: I think the way I would interpret it is you have to have 5,000 people in your ACO, so it would kind of be a chain reaction here, that if they adopt the

idea, which I think there was strong support for last month, that you have to inform the beneficiary and it gives the beneficiary some choices, and then if a certain number of beneficiaries decide we don't think this ACO is going to provide me high-quality care, I'm not going to want to be in it, and then they end up with having less than 5,000 people, then I think they wouldn't be an ACO anymore.

MR. GEORGE MILLER: Basically that could be just one person, or is it a range of people that would not count as an ACO?

DR. STENSLAND: I think whatever the number of people that decide they don't want to be in it -- I think it would work -- let's say you started out with CMS looks at claims, and they say, okay, there's 5,500 people who use your primary care providers. And then they let those 5,500 people know, you know, these are the primary care providers you've tended to use, however they phrase this important communication, do you still want to be in this ACO? And if 600 said no, then you're less than 5,000, and that's my interpretation of how this would all work. Now, there's nothing concrete in law that says it, but that's just to give you a concrete example.

DR. DEAN: On Slide 11, I guess I am trying to understand the broader implications of that structure, and especially -- there's probably no way to predict what the overall effect for the system might be. It all would depend on how many groups you have got in each thing. What about the issue of if you have an efficient organization but you reward them by giving them more money and sort of encouraging them to spend more? It is kind of like somebody is on a diet and they lose weight and you give them a big bowl of ice cream or something.

[Laughter.]

DR. DEAN: I mean, I don't know, but that is the way it strikes me. Does that make any sense?

DR. MARK MILLER: I think the reason that this is being discussed is because the other way it goes is I've been on a diet and everybody else has been eating the ice cream, which is what brings --

DR. DEAN: [Off microphone.] I understand, but maybe --

DR. MARK MILLER: No, but the other point I want to make, this was made fairly quickly, this levels the differences more quickly. But even just using a flat dollar

amount levels the differences. It just doesn't do it as fast. And sort of inherent in those two sentences is some statement of equity, and that's a judgment about where we come out and where CMS comes out.

DR. DEAN: But over the long term, does this get us to overall savings? I guess -- I don't know. I mean --

MR. HACKBARTH: This is a very important question and probably so important it's beyond the scope of round one, so why don't we come back to this in round two. Bruce?

DR. STUART: I have a couple of questions. I do want to make a comment about that, and that is that you actually can assure savings, sort of, here through the target growth rate. So, I mean, that's one way that you can do it.

MR. HACKBARTH: Yes.

DR. STUART: So even if you have variation around that target growth rate, if the target growth rate is below what the expectation, actuarial expectation is, that could be --

I want to thank you for putting in this paragraph about the expectation that we would expect to see persistency in good behavior by ACOs, and I'll come back to

this in my second round of comments, but I have two questions. First of all, you indicate in this chapter that in order to evaluate the impact of providing opportunities for smaller ACOs, which would have by definition greater random variation, you would need to evaluate more than one year of data, and I am wondering whether you have plans to do that and if you have some idea about how many years you would need to look at before you would be able to assess persistency over time.

DR. STENSLAND: Yes. We haven't done that yet. We haven't taken a long time series and grouped them to see how much random variation still exists when you do a rolling average over a series of years.

DR. STUART: I guess my point is that it might not be a long time period. That would be kind of the actuarial issue, is how many years would you need to have before you could expect to do this.

MR. GLASS: The base period is set as an average of three years.

MR. HACKBARTH: Let me just ask a question about the 5,000 requirement. I'm looking at the statute and the subsection is "Eligible ACOs," and then the first subsection

is "In general," and it says, subject to the succeeding provisions of this subsection, as determined appropriate by the Secretary, blah, blah, blah, and then it says in a later section, at a minimum, the ACO shall have at least 5,000 such beneficiaries assigned to it. As I read that, the Secretary is granted the discretion to set a minimum higher than 5,000. The statute says it can't be lower than 5,000, but if the Secretary determines it appropriate, she could say 5,000 is too small. Is that --

DR. STENSLAND: I am not going to argue with the lawyer at the table.

[Laughter.]

MR. HACKBARTH: All right. Good answer, right Mitra?

[Laughter.]

MR. HACKBARTH: Okay. Let's do round two comments, beginning with Mary and Mike and Peter.

DR. NAYLOR: So this was a great next step and really reflected, I think, beautifully the conversation at the meeting. I think the focus on the beneficiaries and the notion of opting out really makes tremendous sense, even though it adds administrative burden, given our history, et

cetera.

I also think the focus on a small set of value metrics and the ones that you defined are really important. The report didn't really emphasize the health status measures, although your slide did, and I think that that is really important, that we get to one or two quality measures, functional status, quality of life, something that really reflects the outcomes that people are looking for.

I also think a movement away from patient satisfaction to more of the language around experience with care, people's experience with care, is probably more in keeping with the kind of direction we are moving in value.

Any kind of strategy that's going to promote ACOs taking full responsibility for the people they're serving, all end services, I think is what we should be really promoting, so the two-tiered approach has, I think, tremendous appeal as the best of the alternatives laid out here to make sure that we encourage providers to get together to work on behalf of these patients, which gets me, I guess, to the question that was around historical spending.

Historical spending from a collection of primary

care providers is based on what they did in the last three years as individual providers. But the ACO is to create a new system, a new design of care, and I'm wondering -- and it's to engage other providers. I'm wondering if that's a great base. I don't know. To think -- maybe I misunderstand what historical spending is, but if you are really looking toward creating a new history with system redesign and payment, I'm just wondering if that's the starting point.

MR. GLASS: Yes. So if you had an essentially uncoordinated set of providers to begin with and you looked at the population taken care of by that set of providers, presumably, if an ACO started coordinating care, it would be easy for them to meet that past target. That is what you are saying, right?

DR. NAYLOR: [Off microphone.] Yes, exactly.

MR. GLASS: Yes.

DR. NAYLOR: [Off microphone.] Hopefully, that is what we --

DR. STENSLAND: And I think that's some of the rationale you all commented on behind the $400 there being a lower target growth amount, and that if you're in an area

where, you know, some of the places David talked about as having really high home health spending or something of this nature, or maybe there is an easier path in front of you to lower your spending somewhere else.

MR. HACKBARTH: On this issue of setting the different targets, for the reasons that Jeff described, I generally support this approach. But I must say, I have some uneasiness about it, and my uneasiness is this. If you carry this to the logical extreme and have more aggressive targets for ACOs in high-cost areas and less aggressive targets for ACOs in low-cost areas, you run the risk that you will have ACOs only in the places where we already have low costs and you won't have any ACOs in the places where we most need them, the places with high costs.

This is a voluntary program, and so people aren't required to participate. And so you have to be sensitive to those dynamics as you try to redistribute in a way that seems more equitable. In mandatory situations where people don't have any choices, then you can aggressively redistribute. But when it's voluntary and they don't have to play, you try to aggressively redistribute, you affect behavior, and you end up, as I say, with ACOs only where you

don't need them, which doesn't make a whole lot of sense.

Mike?

DR. CHERNEW: So three quick concepts -- comments, and I think this was wonderful. The first one is on quality. I actually think there's a role for process measures as opposed to just outcome measures, and you actually have a discussion in the text about why we prefer outcome and not process. I'm not sure I'm quite there yet.

I also think there's a role for a larger as opposed to a smaller set of measures. I think if we could measure the smaller set of things really well, I might feel otherwise. But right now, I worry about teaching to the test type things and other sorts of things. If we just have a very few measures, a lot of stuff gets missed in the cracks.

And I don't think the ER one is actually a quality measure. That's a separate comment.

My second issue has to do with payment related to this slide. The first point is, if you do the 500 part, you will converge in percentages, but you won't actually converge in the dollars, and I'm actually worried about the way that it's all set up, in part because of the seam issue

at year three. You don't know what is going to happen. What would strike me as a little more relevant or another way which they have done in other areas, with all that much success in some ways, actually, you have some sort of national blend, so you have a local match, and so everyone is slowly moving toward the same thing.

And I think to address Glenn's issue, which I believe is really important, when we do the geographic price adjustors for the things that we do now, we're thinking about per unit service, unit cost. And so we have input price adjustors. But in the ACOs, we're bundling spending. So the equivalent of a geographic practice cost adjustor, whatever it would be, would involve spending. You could have multiple ACOs in the same general area, but you would want to maybe give a geographic adjustment in a way that's not just to input prices, but you could conceivably include more than input prices to solve some of that problem, and ideally, you would try and have that converge, as well, to eventually solve the Hackbarth problem, which I think is an important one and how we do this. But I think that it's better to try and do that than to simply institutionalize there's high versus low because we want you in, which gets

to my final and general comment.

We've had this discussion as if there's sort of one model and we're trying to decide what the right model is, and in fact, in my mind, I see there could potentially be multiple different types of models. And if we were more successful than we might hope to be, we would be able to set this up in a way where there would be sort of a road map to getting to where we would ideally want to be, but a transition of models you could be in where you could take more or less risk, have downside risk or not, different ways of enrolling beneficiaries even with benefit design.

I think there's some concern with coming right out of the gate with many multiple models because of these selection issues. Groups are going to pick the ones which they will do best in. I think that can actually be managed and I think it's worth some discussion. But I think in the end, we might be better off if we -- some places that could do really well under certain models, I think shouldn't be precluded from them because we want to get everybody in.

So what I'm worried about is we pick the weakest possible model so you get the biggest possible participation, and then we have a lot of people in a program

that's not as good as it could be. But we have to balance that against having a great program that has virtually no one in it. And so I think there could be some merit to having different models with obviously incentives for groups that think they can do a really good job and get in sort of one that might be the one that most of us would prefer if we could get everybody in it.

MR. GLASS: I think we're saying that the two-sided risk is an additional model to the -- I think. Is that correct, Mark?

DR. MARK MILLER: We think the legislation is fairly clear that there is a one-sided bonus model. Then there's the other language that says, "and other models," and now what the Commission is trying, I think, headed towards is saying, you should definitely be thinking about another model here. I think that's the --

MR. HACKBARTH: The fact that there are multiple models raises a question that we really haven't explicitly focused on, which is so if you have a continuum from the gain, upside only model towards more two-sided models, what force is going to cause people to migrate down the continuum? That's something that you could potentially

build into the program. Now whether CMS can do that strictly through writing regulations or whether legislation is required is an important issue.

But you could imagine, for example, saying the upside only model is available for a limited period of time. It's the entry model. It's what people do to sort of get into the game and develop their organization, test it out. But you have to graduate after five years or some interval. Another approach, and that would require legislation. I don't think CMS can do that under the existing statutory authority.

Another approach is to say, well -- and Herb mentioned this last time -- if you go into the more aggressive two-sided models, you get some benefits. You get certain rules waived. You are not subject to certain things that otherwise you would be, fraud and abuse sort of stuff if you are at risk. Or potentially, you could link it to SGR and say, you're not subject to SGR if you're participating through a two-sided risk model.

I think this question that you've identified of what's going to cause people to migrate down the continuum is a very important policy issue.

MS. HANSEN: Could I use Slide 14 as a guide? Just comments on each one. I think Mary really spoke to some of the components of the beneficiary having afterwards opting out. I know it can be prospective or retrospective. It does seem to perhaps smooth it when -- you know, from the standpoint of the beneficiary, it seems like what they care about most is having their relationship to the physician, not to the ACO. So the ACO becomes kind of an entity that we know of, but from a beneficiary's standpoint, it doesn't make a whole lot of difference. And I think what does make a difference is if their provider, their physician or primary care provider is happy in the ACO, that will likely make it easier for the beneficiary to be happy, because I think the managed care issue is when you have unhappy providers, you have unhappy beneficiaries.

The other thing is the small set of quality measures. I just want to affirm what Mike was saying, that there are measures that are in process, so to speak, not in process measures, but measures that are in process, because CMS has put out this call for looking at multiple morbidity issues rather than kind of linear disease management kinds of measures, coupled with the fact that I believe NQF is

beginning to have a focus on the whole issue of multiple morbidities.

And the reason I raise that is with the health status aspect that Mary said, I really hope that there will be a highlight on what the profile of the beneficiary is so that we make sure that the beneficiaries that are 75-plus with multiple morbidities are kind of seen as a visible entity in any of these ACOs.

The limitations of small ACOs, that is something that's there, and I know that visits were made to some PACE projects and all, because ironically enough, you know, PACE projects are kind of ACOs on steroids relative to the fact that it takes full risk and all. But the average size of those quotes virtual -- actual ACOs oftentimes is only 350 enrollees with a very targeted population, mind you. But just thinking about the possibilities of what size are, but so long as you have a targeted population that's there.

I think the benchmarks reflecting use, Tom's comment really captured my question, and the last point was the two-sided risk model with corridors. I would highly support that option. It's one of the things that we found in our experience, having a three-year risk corridor set of

experiences with any start-up of PACE models seemed to work. And then you can take the wings off, so to speak, in year four and you're on your own. But implicit, what it means is there is culture change going on because of the changed incentives, changed behavior, and with the two-sided risk, the upside and the downside, you are always aware of. In other words, that becomes the little warm fire under our derriere in order to kind of keep our attention focused of the upside and the downside. So I highly recommend that that be definitely one of the options.

MR. BUTLER: First, one general comment. There is a whole bunch of people that are skeptical that these things will work at all, yet the market is responding in a way that this is the real deal, and if there's one thing coming out of health reform, it's affecting mergers, it's affecting alignment of physicians, a whole ton of things. So I think that while we can say technically it's got all these complexities, how these regulations come out, people will be betting on the future and making very important decisions about aggregating health systems and physicians. So I think we need to keep that in mind.

Now, on Slide 14, I'll go down this, too, and try

to be as specific as I can. So the two-sided, yes, definitely favor as saying bonus only is not, you know, enough.

Then I start getting more nervous as you do, Glenn, on the benchmarking on -- I'm working from the bottom up here. I'm reflecting levels of use. I think we would want barriers of entry to be relatively low right now if we, as we have in the past, want people to begin to test the model. And how do we this, I don't have an exact, specific additional recommendation, but you said, or we said that you have to have a threshold. In a bonus-only model, you've got to do something more than just, you know, break even on last year's performance. Yet providers are going to be working on readmissions and all these other things and giving up revenue, as we know, before they even hit the threshold, and then that gets to a little bit of Herb's point of maybe having some waivers on readmissions or whatever.

An alternative might also be just to simply cap the bonus that you could accrue. So maybe it's a modest amount. So the threshold may be not low, but the windfall is -- you know, you could cap it at a relatively modest amount initially in terms of what you could actually receive

by beating the target.

Now, moving up to the limitations of small ACOs, I said at the last meeting, and I still agree, that 10,000 is a better threshold than 5,000. I would say that most systems, though, when they are organized, in the end, they are going to be down in primary care offices that will be behaving at a level that is much lower than 10,000. So I think it is not unimportant to say the infrastructure, the ability to kind of manage the continuum, requires a system of care. But, in fact, we do want to influence behavior in relatively small offices, because that is where the rubber hits the road. So I wouldn't mistake it as saying a three-person internal medicine group should not be engaged in all of the incentives, but, in fact, the system of care provided is going to cost a fair amount and we want it sustainable over time.

I'm also a little worried that we focus so much on primary care. Those that have been in capitated environments know that the coordination around diseases very much needs to involve the specialty people in helping make all of that happen. That's what really is effective. So if we just make it feel like it's another gatekeeper model,

it's not the right message. That's just an aside.

On small set of quality measures, I agree and I would underline "small." I don't think that we're great at this, and I don't think -- as important as it is, I think, coming out of the gate, it's not as important.

And finally, on informing beneficiary, I've thought about this more and I don't really like where we came out in saying, you know, the opt-out part, and I'll tell you why. I fully support putting a sign up, whatever, we're a participant. This office participates in ACOs and describing what that means. So if you do the opt-out part, first of all, the beneficiary can opt out anyway. They can go anywhere they want under the bonus-only model.

But secondly, again, the small offices may be participating in a bigger system of ACOs, but their compensation, in fact, may very well be directed at the local level, the way they compensate in their system based on their individual performance. And believe me, you could encourage opting out at that local level in a way that could dramatically affect the impact at a local office, relatively few patients. I don't know. You really ought to -- now that you're really sick -- there could be some unintended

consequences of doing that opt out. But informing that this office or this group of physicians is part of a pilot, I think is important.

MS. BEHROOZI: One point that -- actually, I want to say thanks for the report. Thanks for making it so concise. Cori and I were talking about how much fun it was to read a short paper. Thank you.

A point that Bob mentioned, there's this conflation out there. You know, you talk about the market and how people are responding, and I can't tell you how crazy it drives me to hear people using the term medical home when they mean ACO and ACO when they mean medical home. Now, maybe that only matters to the wonks, but I think that when we're talking about informing beneficiaries about what's going on, it's very important to be clear that ACO really -- the accountability part is really about payment. I mean, yes, of course, it's about measuring quality. Yes, of course, it's about enforcing high standards of beneficiary centeredness and all that. But it's not about getting a designation based on just the standards that you meet. It is also about how you are going to get paid.

And so I do think that that's what matters about

beneficiary -- or that's why it matters that you allow beneficiary opt out, as we've talked about the managed care backlash and all that. But I don't think that that necessarily means you have to make it look like a big, bad, scary thing, that it's only about payment. Of course, it's about all of those other things, too.

And in fact, we haven't talked about this, but maybe I'm missing some big reason why we haven't talked about it. How about beneficiary opt-in? How about if somebody -- if you're talking about how you would use basically two-year-old data to prospectively assign people to ACOs and then allow them to opt out? Maybe there's somebody who's been in the practice for a year and a half or whatever, has been seeing doctors in that practice, who it would be good for the Medicare program if that person were sort of counted in -- you know, you could look at their spending wherever they were previously treated and if this practice was really on the track, they could be part of it, because maybe they would think, wow, this group is going to be focused on quality outcomes and this group is going to -- you know, maybe there are benefits in it for me, even if we don't go to reduced cost sharing, but I will have lower out-

of-pocket payments because I won't get referred for too many unnecessary tests or that kind of thing.

So I don't know if there's any big reason that I'm missing why we couldn't think about opt in.

MR. HACKBARTH: Well, there are two distinct issues at play here. One is patient engagement, preventing backlash, and the appeal, at least to me, of the opt out was striking a balance between encouraging maximum participation by patients with an eye to what Peter said, that under this structure, they can go elsewhere if they are really unhappy, and they are not constrained. So an opt-out allows people the opportunity to get out and make sure that we have got that safety valve, if you will.

Opt in, I guess, my guess would be would result in lower participation just because of the inherent inertia that exists.

MS. BEHROOZI: I mean both. I am sorry. I mean both. I don't mean except -- I don't mean to --

MR. HACKBARTH: And that takes me to the second issue. The second issue at play is how you set the targets and who is counted in the base year and just the mathematics of it. And opt-in complicates the task of what's the target

for this group because you have no experience for them.

MS. BEHROOZI: Not necessarily, because you would have their experience with the other providers that they had been with over whatever period of time they were in Medicare, right?

MR. HACKBARTH: But that might be -- disadvantage the ACO if the patient was at a high-cost provider -- well -

MS. BEHROOZI: No, that would be better --

MR. HACKBARTH: That would actually help them. You want to recruit from the high-cost --

MS. BEHROOZI: Yes. That's what I'm saying. I think it could actually be good for the program, because maybe you could draw people from high-cost providers to providers who are now committed to bringing the costs in lower.

And I think it's actually consistent with the two-sided risk model, too, because to me, there's an issue of credibility, right. If people want to get into the game, having a little skin in the game shows that they're really serious about that, and allowing them to recruit people, or say, you know, sort of market themselves, look, we are at risk for delivering high-quality, efficient care, and then

people are fully informed about what that means. As I said, it involves payment. It's not just a medical home.

MR. HACKBARTH: Yes. So I hear your point now, and let's think some more about that. I'm a little worried about time because we are running over substantially.

Other round two comments?

MS. UCCELLO: I'll be brief. I just want to echo the support for the two-sided corridor and say that the way that it's structured makes sense, especially in the context of it's an option alongside the bonus-only and it's voluntary. So I think that makes this make sense.

And a quick question. What happens with 65-year-olds? Then they can't be in? They're not going to be in on this?

MR. GLASS: I don't know that it's clear on that. I guess you could do something analogous to whatever they do with 65-year-olds in MA.

DR. CASTELLANOS: Thank you. Just two points, and really, both of them have been briefly mentioned.

I've never seen so much enthusiasm in the medical community towards anything that I'm seeing now, and it's good because we've got communication with the hospitals now

and the physician community. And I really think it's a point of maybe really energizing the Medicare system.

I'm a little concerned about cutting back below 5,000 or 10,000, the reason being is that in the United States, only 20 percent of doctors are in large clinics, and most of them are in smaller communities like I am. And to exclude that population of physicians and the enthusiasm and trying to work with the system is somewhat discouraging.

Now, I understand size is important. I understand the random variation and the pool size is important. But, you know, in the bonus model or the keeping the concept of the ACO to control costs and excess volume is really important in the community. And if you can get the doctors in the hospitals, all of us working together, I think it's important.

The second point is the beneficiary. You know, we're talking about providers here and very little has been talked about the beneficiary. Jennie, you mentioned it, too. But you've really got to think about it. What's the beneficiary getting? Well, high-quality care. Well, I expect that from my doctor, no matter what. Coordinated care, I expect that, no matter what. Efficient provider, I

expect that, no matter what. Now, maybe I'm not getting it, but I expect that, and each patient or beneficiary expects that.

So what are you really giving? What is the incentive to the beneficiary? And I think we have to start thinking about that, because they can drop out and see the same doctor, and as Jennie mentioned, the relationship is between the beneficiary and the physician. So I think we need to think about something as an incentive for the beneficiary. Thank you.

DR. BERENSON: Two quick points. On the quality metrics, I'm somewhere between Peter and Mike, I guess. In general, I support MedPAC's move towards recommending outcomes more than process measures, and I also don't think the process measures we have give a global assessment of quality. They tend to be focused on primary, secondary prevention. But those are particular areas that we can detect stinting, and as we have stronger measures, I mean, stronger payment models that actually do involve some risk, I think there is some value in assuring that some basic preventive services are being provided. That is what IHA in California, I think, has successfully done with the risk-

bearing medical groups out there. So I wouldn't have an exhaustive list, but I do think some of the process measures, particularly around these stinting areas, does make sense.

On the issue that Tom initially raised and Glenn joined on, on the concerns about rewarding low-payment areas, et cetera, I think we should go the way we have laid this out. I think it was a MedPAC report, I'm not 100 percent sure, that showed the lack of correlation between baseline spending and rates of growth in spending. And so Grand Junction that's been in the news recently had a high rate of growth. It may be that they're starting at such a low base that that high rate of growth is reasonable.

I wouldn't want an ACO program that just had inefficient areas in it, and as Herb raised last time and as we've talked about, if one of the incentives to go into an ACO is to get out of sort of the broad national approaches that we're taking to squeeze down on payments, I would want good organizations to have an opportunity to be in a different system where they are accountable for their own performance and not part of the whole sort of pressure.

So I do think we have to find the balance between

making it so impossible for the high-cost areas to not want to play and give unnecessary rewards, but I do think we can find that balance and we should try to.

MR. KUHN: Two quick areas. One, on the quality measures, I'm pretty much in alignment with where we are in our recommendation, although two areas that would be interesting if we could look at pretty hard. One, I do think that care transition measures ought to be pretty up front in our list because that's obviously what we're trying to incent and what we're trying to encourage here, so I would like to see us have a bias towards that. Plus I'd also like to have us biased towards meaningful use measures and what we can map from EHRs, because again, that's a bias where I think we want to encourage adoption and the best we can make that play.

The second issue I'd like to raise is the issue on the small ACOs. I think enough has been said about those, but one area we haven't talked about that I just kind of want to surface that we might want to think about sometime in the future is the area of the coding creep that ultimately will play into this. You know, within the PGP demo, if I recall right, they do a normalization process

every year to deal for coding adjustments that are out there. The same thing with MA plans. We have done it on fee-for-service. Our last exercise, as we all know, was the documentation and coding improvement initiative with the IPPS rule.

But what I do worry a little bit about is with smaller ACOs, and I'm with Ron, I really want to make sure these are viable options in rural areas and smaller areas around the country, that their ability to code as aggressively, perhaps, as larger areas might not be there, and so if there is kind of a national normalization process, would that further disadvantage smaller ACOs or make that not a viable option for them. So I'd like to see us kind of look at that some time in the future.

DR. KANE: Yes, for the small ACO, and I think Mitra was talking about medical home versus ACO and the confusion, and I'm wondering if we shouldn't try to clarify what the differences and then how one might transition, so that if one is trying to be small ACO, but say beneficiaries opt out or go below, that they become automatically somewhere between a medical home and an ACO. And the difference would be that they start to get bonuses for

better management of A&B services, but maybe not as complete as an ACO.

So I'm just trying to think of ways to make transitions between the medical home and the ACO for these smaller groups, and bonuses, not necessarily penalties, but bonuses for how they manage the broader A/B benefit, at least in specific areas, but trying to create sort of a learning -- again, these sort of transitional models between the medical home, which is not really -- they're sort of, I guess, nominally being viewed as managing A&B, but not necessarily at the same levels as an ACO and so are not at risk for it. But then there's something in between there where they do it really well, they get a bonus. It just starts to bring them more into ACO land as they get the expertise in the systems.

I keep hearing from the physicians I know that they're starting to think about oh, gee, I should be a medical home and/or an ACO. And they're saying: Now how will I find out where my patients are getting their care?

I don't think people have really thought too much about that. I mean I know the VA. It's basically you get the nurses to run around calling, and you try to educate

your patients. But should there be some thinking about how do we make sure that the non-ACO provider (A) asks the patient if they're in an ACO. They may not know, but tries to find that out. And then if so, they have some obligation to report that data to the ACO.

So I mean there's a real information gap there. And when you start thinking about how free-flowing these are, where the beneficiary can go anywhere, there may be a need to facilitate how the ACO finds out what the patient is doing that goes beyond just go find out, call and see what you can do. I think if there's some way to facilitate that.

And then I guess the last comment I had is about how do you get high-cost ACOs, high-cost organizations to join an ACO. I think a lot of the reason there's excitement out there is it does offer a great opportunity to finally start doing the right thing and getting rewarded for it, which is managing care and making better quality.

But I think also there's a huge uncertainty there about what's going to really happen in 10 years or something, and that uncertainty can cut 2 ways. One is well, since we don't know we won't do anything, or we're pretty sure something much more dramatic is going to happen

in 10 years.

And I'm wondering if we can't try to get, maybe recommend, and I'm sure this is something Congress has to do as opposed to CMS, but try to get some sense of this is a nice, happy experimental period, but by 2015 these things are going to be mandatory. Or, these are going to be the standard, and if you're outside the standard the penalty is going to be X.

Just some reduction in the uncertainty because these are, as Peter said, huge investments to make, and for all we know they could go away. The whole movement could go away. And the lack of commitment to the movement by the payers, by the government is a little unsettling when you realize the kind of bets people have to make.

So I'm just wondering if we can't find ways to try to say, yes, it's a little less uncertain than it looks right now because by 2015 there will be a major -- I don't know. I know that's just wishful thinking, but I think that would help encourage more of the high-cost places to want to go into the ACO.

MR. ARMSTRONG: So actually building on your last point, I would just say -- and Peter had made this point

earlier -- the uncertainty that you describe, at least in my world, is inspiring people to do a lot of things and create what are being labeled many different things right now, but they're sort of loosely understood to be something like ACOs.

Just a few brief points, although I would really endorse a lot of what's been said already: First around the assignment and identification of patients, now I've said this before, but I do feel strongly that it needs to be transparent. The providers need to know who these patients are. In fact, I think there's real merit in this idea of limiting the opt-out as a choice for the beneficiaries, although I understand the value of it. It creates that these provider groups are going to need to know who these patients are and build relationships with them over the course of time, and it will take time for them to see the savings that we're trying to create through an ACO. If patients are moving in and out of those practices, it makes it very difficult for that to happen.

In fact, I think we probably understate how much information, as an example, these practices will need from us and from others about those patients and where they're

being referred to and who the other providers are that they're interacting with, whether it's within the ACO or not.

So for all those reasons I think just knowing who those patients are is critical to actually achieving some of our goals.

Around quality measures, only briefly, I would agree that I think you really need both process and outcome measures. We've talked about patient satisfaction. I think we're seeing experimentation with some really great patient engagement measures these days that help you to understand how actively are patients engaged in managing their care, working with their providers, accessing their electronic records. These kinds of things might be also valuable for us to insert into our quality measures.

Finally, I just would say that I really do agree that we need to look beyond the bonus-only methodology, or model, for reimbursing the ACOs. I'm not sure if they're tiered or how these alternatives get lined up, but to go to two-sided bonuses or some kind of capitation arrangements I think are really the way to create the kind of financial structure that will advance the outcomes we're looking for.

I would also just acknowledge, reading this, particularly being someone who works with large groups that care for primarily fee-for-service Medicare patients, but also being deeply involved in MA plans, that the complexity of some of these payment structures we're talking about sound an awful lot like what MA plans do, and that we should be thinking about how we might -- we shouldn't discount anyway the role that MA plans might play in helping us to build some of these capabilities within the system.

MR. HACKBARTH: This is an important point, yes. All my instincts based on my own professional experience are similar to yours. You want maximum patient engagement, and some of this goes back to the points that Mitra made. You like enrollment. You like engagement. You like commitment, more risk. You can't have patients wandering around the system.

But basically what we're doing is we're reinventing Medicare Advantage when we talk about this, and we have to keep in mind that the goal here is different. The goal here is to create something within the confines of fee-for-service Medicare that gains at least some of the advantages of Medicare Advantage, but without just making it

into Medicare Advantage all over again. So there's a balance to be struck there. I'll leave it at that.

George?

MR. GEORGE MILLER: Yes, just briefly, I'm glad you articulated stating the goal again because that helps focus our thoughts, at least helps focus my thoughts. But I do want to endorse the two-sided risk model giving more of an option, and I really appreciate what Jen said about the relationship between the physician and the patient and starting to make this work. As Ron said, there's a lot of excitement out there, but to really make this work.

We all remember the horror stories of managed care. Well, a lot of that problem in managed care was led by physicians who were not happy. So if you really want this engagement to work, you've got to have the physicians onboard and supportive. And again, Ron said they're excited, which is somewhat refreshing.

I also wanted to address and raise some concern. The reason I asked the questions about if you can opt out of smaller groups is making sure there are good examples in rural communities. Tom's examples about how ACOs can work on a smaller level. But how we provide that infrastructure

to make that work, I'm not sure, but I want us to at least take a look at that.

And then finally, I certainly endorse meaningful use measures that Herb mentioned. I think that's an important quality measure as well.

DR. BAICKER: I want to echo what Peter said about informing the beneficiary. Information is great, and there should be big signs everywhere, but I'm very nervous about beneficiaries being able to opt out. It makes sense for them to be able to reallocate and say: Actually, that guy is not my primary care provider; this guy is now. That makes sense.

Having a beneficiary opt out of the system, you already have, and see the same provider. You already have ACOs voluntarily participating. If then a voluntarily selected subset of their patients actually count, I bet everybody is going to be above average, and that's a real risk there in letting -- I know beneficiaries are the ones choosing, but providers surely have some influence over getting their high-use beneficiaries to opt out voluntarily.

A small set of quality measures, I would be interested in being able to characterize the quality

measures as ones that are likely to proxy for broader quality or likely to compete with alternative uses. We know in some of the hospital-level measures, if you target some patients, that can have negative effects on other patients because you move resources towards the things that are being measured, as opposed to something that is likely to have positive spillovers to other patients. So I would want the narrower the set of measures are, the riskier the probability of moving resources towards that set of patients at the expense of others. So that's one way to evaluate those metrics.

And the last point is thinking about small ACOs. On the one hand, we all have two hands; we can't be afraid to use them. On the one hand, if you have small ACOs you risk the noise and the problem measuring, and you're going to have a lot of bouncing around. On the other hand, I don't know the distribution of potential ACO sizes, and I'd love to see some information on if we set the threshold at 5,000 here are the number of beneficiaries who might possibly be eligible. And if we set it at 10,000, here are the number of beneficiaries who might possibly be eligible.

And I don't know what the optimal size for an ACO

is. It could be that in fact you have your biggest bang for the buck in creating these things in the 5,000 to 7,000-person range that the networks who are already serving 20,000 people have got this under control. Or, it could be exactly the opposite. I just don't have a good sense. So in choosing the threshold you want to consider not just the noise, but the potential scope of the benefit.

MR. HACKBARTH: This patient choice thing is really, really important. And I don't disagree with what you say about the risk of selection. Having said that, that's not unique to this program. The same risk exists within Medicare Advantage, in fact, maybe even more powerfully so.

DR. BAICKER: And we have some issues there.

MR. HACKBARTH: Right. To say to a Medicare patient, your physician and perhaps the physician's hospital have decided to enter into a new financial arrangement with Medicare, and part of that may be that they will have an economic benefit from changing your care, and the only way you can avoid that is by changing your physician -- that's basically saying we've changed fee-for-service Medicare. You no longer are able to keep seeing your same physician.

We've just pulled that option out from underneath of you. That's potentially a problem.

DR. BAICKER: But every time we change the fee schedule, that happens. Now this hospital is eligible for a bonus payment, and the only way you cannot be subject to that is to go a different hospital.

MR. HACKBARTH: Yes, yes.

DR. BAICKER: But that's inherent in the program, I think.

MR. HACKBARTH: Yes.

Tom.

DR. DEAN: I would just echo what was just said and also Peter's concerns. I mean I think somehow we need to figure out a way to present this to beneficiaries, to show them what they stand to gain. I think Ron said the same thing. I mean what is there in this to benefit from if you just present them with this very complex theoretical model. You know they probably are going to all run the other direction. And yet, long term, we would presume there is benefit, but the question is how to explain it to them.

I guess I would say I liked the quality measures that were laid out, partly because there was a short list,

but partly because the ones that were listed really reflect the care of a whole range of conditions. And so often we see quality measures based on hemoglobin A1 and blood pressure control, and that can really result in what Kate just said about you focus in on certain conditions and you may well neglect other things.

Finally, to get back to how you reward the best performance, I wonder if there aren't, and this has probably already been said, but we need to look for other types of rewards besides payment rewards like regulatory relaxation and things like that that might help, or ways that organizations could attract more enrollees through I'm not sure what. And we need to, I think, look for other options besides just dollar rewards.

DR. STUART: I think if we were to take votes on some of these sub-issues, that we probably could reach some consensus. And the two that I think are really important here are the opt-in, opt-out, and I opt for the getting rid of the opting. I'm not a fan of opting here. I think that we still have the MA plans available out there, and both providers have opportunities to establish these types of organizations, and beneficiaries have the opportunity to

take them.

And I think it well may be that ACOs ultimately adopt or ultimately move more into a capitated framework, but I am really concerned that we not put arbitrary impediments to innovation based on size and risk. I'd really like to separate those.

And I think that Peter and Ron are right on by saying that the rubber hits the road with the small providers, and so what we need to do is to provide incentives for them to do the right thing without harnessing them with undue risk.

So having said that, how do we do that? And it strikes me that there is a whole range of things. Even though I think that the two-sided risk model is right, the two-sided risk model is not a solution for small ACOs. What it does is that it holds Medicare harmless because some will be up and some will be below the target. But small ACOs are going to have trouble trying to figure out whether they did something that resulted in a bonus or a loss, and they're not going to find it easy to do that within the context of a one-year payment.

So the argument that I made last time, about

having a structure in which the payment is tied to some persistency of performance over time, I think is really essential here, and particularly when you put that in the context of having to make arrangements that will cover three years or potentially more. I think that that provides a mechanism for that.

And I also think that the way this is sold to the market and the language that we use is important. I used the term last time about the potential for clawbacks if you were to have a payment and then -- you know I should have not have said that. Bad.

[Laughter.]

DR. STUART: Nobody likes clawbacks. So even though theoretically that might work, you don't want to do it that way.

But you could do it another way. I mean you could set up funds so that individual ACOs would earn a certain portion of their bonus, depending upon the persistency over time. These could even be interest-bearing accounts. You know, with the interest rate at 0.3 percent. At least at the present time, that would be reasonably cheap to do that.

But there are also private sector ways that this

can be handled. We haven't talked about the reinsurance market. Well, I mean reinsurance is around to help the small risk problem or to help the outlier problem. So I think that that's something that we should think about.

There are also ways that you can organize risk within the context of the provider community. We're thinking of ACOs as being single entities, but ACOs could be cooperatives. Or, it could be that there's a large ACO that has small, little practices that somehow have arrangements with a large organization that would handle this risk problem.

So I just want to make sure that we focus on what the providers are doing that is going to result in improved care and ultimately lower cost, and not simply say okay, well, risk is what drives it all. Let's have risk as kind of secondary and say let's make sure that we organize the process of managing risk well, without doing harm.

DR. BORMAN: Not being smart enough to comment on all the statistics and actuarials in provisions, maybe just a couple of altitudinal thoughts. Number one is as we look at ACOs, I think given the excitement and all the other things and all the potential benefits, we're in a situation

where we'd like to see them succeed or at least if we're forced to conclude that they failed, that we've given them the proper structure in which to try and succeed. I think that's reasonably important.

So if we do that, we then have to say, what evidence do we have now about various successes? And it would appear to me there probably is, at least what we know about entities that seem to function as we envision an ACO, they do tend to be larger and have a lot of resources. On the other hand, we know that we want lots of people to be able to participate, lots of patients and lots of providers, and that gets us to the folks who aren't so big.

And maybe we need to think about: Is that a subgroup in which we advocate that those things -- because we want them to succeed, but they may succeed in different ways -- are better managed through the Center for Innovation, and defining things in that way? Just because I think we take a big risk here about coming out with answers that we either don't understand or don't like or that are not correct by virtue of trying to please all the people all of the time. I think probably that's something we need to consider.

And then another thing is as we talk about an ACO and look at the idea that at the end of the day we want to provide at least as good, if not better, care at lesser cost. The things that are less dependent on behavioral change, and behavioral change takes a while, are things like eliminating redundancy and facilitating transitions.

I think if you look at, as Herb alluded to, as you look at some of the process measures that you ought to retain, things about transitions and meaningful use become more important because those can drive savings, not entirely independent of behavioral change but to some degree. So as we look at features that we think are appropriate. Things that enhance efficient transitions and limit redundancy probably are the things that bring us the greatest value in the process.

Then just a point of ignorance would be that do we envision that there is sort of something like a conditions-of-participation definition here. There is some stuff in the statute. But does the Secretary, in the rule, will there be some things that are kind of analogous to that, and is that where some of the process stuff really is because we don’t want it to be an “if” thing?

There are some things we absolutely believe ought to be in there, like the things that measure, or an index for stenting or some of those kinds of things. They need to be just kind of out there as rules, if you will, and then we look at -- although I personally believe a balance weighted toward outcome, but is still including some process, in the end probably is the better protection.

And then lastly would be you know there is something here of a grand experiment, and so we need to make sure that we encourage that there's enough, a dynamic enough process to update it, and recognizing that we need to provide as stable a platform as we can.

There's a tension here with also being able to respond as we find out how these things work. Do we find out that this best guess, three-year data background benchmark wasn't the best thing? Is there a way to interval change it?

I think that it's going to be hugely important to have those revision modification processes kind of built in and understood, to the best of our ability. Otherwise, it will take us X years to do this and Y years to get the data. By then we'll have such different system changes, we'll be

back at ground zero. So we need a dynamic process or at least a commitment to that.

MR. HACKBARTH: Well, this has been a rich and valuable discussion. The issue that stands out for me in this conversation is this issue of patient choice, selection; however you wish to characterize it. I confess to having quite strong feelings in favor of giving patients the option of getting out.

The reason I feel strongly about this, the thought experiment that I do is let's assume the best case, that ACOs prove to be effective in doing all the things that we want to do. They change the care that's delivered. They slow the rate of increasing costs. They achieve significant one-time savings.

What does that mean in the real world? What it means, among the things that it means is that there are going to be losers in the provider community. Some people are going to be losing a lot of revenue. There is going to be a redistribution of how the dollars are spent, and they're going to have a reason to try to stop this, disrupt it, discredit it.

I'm not imagining this. We've been through this

experience before, in the nineties with managed care. We know what happens, what tactics are used to discredit these ideas with patients and how effective they are. So if we go down the path of saying all of this is going to happen behind the door, and the patient doesn't have the opportunity to act on their anxiety about it and say this makes me uneasy, I don't want to be part of it, I think we are setting the stage for what we saw so painfully before.

So I think the minimum that you can do is advise them, and if they really don't like it they can say: I want to keep my doctor. Don't force me to change my doctor. I just don't want to be part of this. It makes me uneasy because my cardiologist is saying bad things about it. I just don't want to be in, but I want to keep my primary care physician.

I think that's the reasonable balance to strike, to avoid what we know to be a severe risk.

DR. BAICKER: Could I offer one potential compromise just to think about? I'm nervous about a 10,000-person ACO or 10,000 patient organization picking the 5,000 patients they want to have included in the ACO. You're nervous about patients not having the choice of saying I

like my doctor, but I don't like the ACO arrangement. Could participation in the ACO be conditional not only on a threshold number of patients but on a threshold participation rate?

So you have to have at least 90 percent of your patients participating. If fewer than 90 percent participate, then you're not an ACO.

MR. HACKBARTH: So that's an idea. I'm sorry. We're way over time. So we're going to have to think about it offline and now move to our next presentation. So, thank you, David and Jeff.

So the next presentation is on a report on a panel that we had on identifying high- and low-value services.

[Pause.]

Okay. I'm just sort of figuring out the schedule here, and we really had to devote that time to the ACOs because of the CMS work that's going on, so I apologize, Joan, for impinging on your time.

So what I'd like to do is shoot to wrap this up at about 5 after 12:00. That gives us 45 minutes. Then we'll have a brief public comment period before lunch.

DR. SOKOLOVSKY: Once again you're looking for the

fast talker to follow.

MR. HACKBARTH: We came to the right place.

DR. SOKOLOVSKY: Good morning, everybody.

In your deliberations last year about reforming the Medicare benefit package, a number of you expressed interest in the idea of varying beneficiary cost sharing based on the value of the services they were receiving. A few weeks ago, we brought together a panel with diverse experiences with this issue to discuss how one would go about identifying high- and low-value services.

The panel provided a wealth of ideas to think about, and we found the discussion so thought-provoking that we wanted to give you a summary as soon as we could. We asked the panelists about how they would go about identifying high- and low-value services, what their experiences were trying to implement benefit designs that take the value of services into account when setting cost sharing, and how this experience could be useful for Medicare.

Our panelists generally agreed that reforming the benefit design to encourage the use of high-value services and discourage use of low-value services was a good idea.

Some general themes emerged. The value of a service often depends on who gets it and how it is priced. Public acceptance of a benefit design based on value depends upon the process used to identify high- and low-value services. That means that both beneficiaries and providers should be actively involved in decisionmaking. Some thought this worked best on a local level. All agreed that beneficiary and provider incentives must be aligned. Medical management should also be part of benefit reform, they said. Finally, panelists said that beneficiaries would be more open to change if they had choices.

In this presentation, I will try to present the themes that most panelists seemed to agree upon and highlight some of the issues where there were differences in approach.

The panel consisted of 11 participants. They represented a range of perspectives, including academics, employers, benefit consultants, a consumer advocate, and representatives from health plans. It included physicians, a nurse, and two pharmacists, and it was moderated by Peter Neuman of Tufts University.

Most panelists had a number of roles and came at

the issue on the basis of multiple experiences. All had experience either designing, implementing, or evaluating benefit designs that include identification of high- and low-value services. Again, although the topic of the panel was how to identify these services, panelists quickly moved to discussing how a benefit design that makes these distinctions could be implemented in Medicare.

We did not define high- or low-value services. We wanted to hear how panel members themselves would define it. Panelists agreed that much more work had been done identifying high-value services, but they thought there was sufficient information to begin identifying both high- and low-value services. We heard the most varied definitions of low-value services. Their answers ranged from categories of services -- for example, services that harm people or provide no benefit -- to specific interventions for specific subpopulations. Some suggested a service could be low value if it were provided in ways that went beyond the clinical evidence of effectiveness -- for example, a drug given for unapproved uses.

Another category of service is a service that costs much more than a comparable intervention without

providing any additional benefit. Others mentioned services that have very high marginal cost while providing very little health benefit.

Two general issues emerged: A number of panelists said that most services provide value to some people. If the determination is too rigid, people may not get services they need. For example, say that all high-cost imaging should have very high co-payments. On the other hand, if the incentive covers all use of a service that is high value for some people, cost sharing may be waived for populations for whom the benefit is not proven, and costs for the program will increase. The issue here is whether you can design a benefit that targets varied co-payments to specific subpopulations. This kind of targeting by subpopulations may raise both ethical and technical issues.

Another panelist said, and I quote here, that "low value is a function of mispricing." For example, two treatments may be equally safe and effective, but if one is much more expensive than the other, it becomes low value. And Nancy will be talking about this issue more later today.

Some panelists suggested that the most important thing about identifying high- and low-value services is the

process with which it takes place. The process should be open and transparent. It should be based on a set of guiding principles and medical evidence. And, first, there must be a decision about who is going to make these identifications and what the burden of proof should be before something is defined as either high or low value.

Beneficiaries, providers, and other stakeholders must take part in the process. One panelist suggested that before any services are identified, a public discussion of the priorities is necessary. Why are we doing this? For example, you can talk about a discussion of harms done by providing low-value services. One panelist suggested that the priorities have much more resonance when they can be related to an individual's personal experience. You are more likely to have buy-in if you focus on an individual's bad experience after receiving a low-value service or how Medicare spending, for example, is taking an increasing bite from their Social Security check. They say that will have more resonance than if you talk about the billions of dollars that could be saved for the trust fund by discouraging the use of these services. Others suggested that it was easier to set priorities on a local or state

level rather than on a national scale.

Panelists agreed that raising or lowering co-payments for a service will have more effect on utilization if the incentive created for beneficiaries is aligned with the incentive that their physicians have. Attention focused on P4P programs. One physician spoke about his frustration when a health plan rates him on the percentage of his eligible patients who receive colonoscopies at the very same time that it raises cost sharing for the same service for the members.

Panelists also noted that Medicare supplemental policies must be aligned with benefit changes. As we have discussed before, first dollar coverage could blunt any incentives created by variable cost sharing. Panelists mentioned not just Medigap but also employer retiree plans.

Some panelists suggested that to the extent that private payer incentives are also aligned in the same way, the effect on the use of high- and low-value services would be magnified.

Others suggested that medical management needs to be in sync with the identification of these services. For example, one plan charges higher co-payments for advanced

imaging without precertification. If your imaging is certified in advance, you pay one co-payment. You pay a no co-payment -- you can still get it, but your co-payment will be higher if it isn't authorized in advance. Panelists mentioned that medical management is particularly important for lower-income beneficiaries because higher cost sharing would be impractical.

We heard a lot of suggestions about how the process of identifying services should begin. Most agreed that the process should be incremental. Identifying low-value services could start with services that harm patients, for example, more talk about the risks of overexposure to radiation caused by too much advanced imaging.

Another panelist suggested a data-driven approach. First, look at the services that cost the program the most money and use evidence to determine their value.

Another suggested starting with Part D. Under the drug benefit, beneficiaries are used to co-payments varying depending upon the tier in which their drugs are placed. Tiering could be done based on value. The panelists also suggested there is currently more comparative effectiveness information available for medications.

Another suggested that ranking individual services was too difficult and politically charged. The program would gain more traction by tiering co-payments to steer beneficiaries towards the most efficient, high-quality providers. One participant talked about a plan that does both. For certain conditions, the plan uses evidence-based guidelines to define care pathways. The pathways may include referrals to specific providers who have demonstrated use of evidence-based high-quality care. Patients who choose to follow these pathways are charged lower co-payments.

One panelist suggested that Medicare should move the burden of proof to pharmaceutical and device manufacturers to show that any new therapy is better than the standard of care or else their service would be considered of lower value.

One idea that generated quite a lot of discussion was the introduction of what one panelist called a graded benefit. This would be a Medicare fee-for-service benefit that would be offered to beneficiaries as an alternative to traditional Medicare. Cost sharing in this benefit design would be based upon the value of services and/or the use of

high-quality efficient providers. The option could apply to new Medicare beneficiaries, and beneficiaries who choose this option might have a separate Part B premium and opportunities for reduced cost sharing if the plan results in savings.

Panelists agreed that beneficiaries would be more likely to accept such a benefit if they were presented with choices. They discussed the tradeoffs on how these choices should be structured. Some of this seems to go back to what we were talking about the last hour.

An opt-out model where beneficiaries are enrolled in the new benefit design, as in Part B, unless they actively choose not to participate, would likely result in higher enrollment in the graded benefit at first, but some panelists thought it would be more likely to lead to dissatisfaction. If beneficiaries actively chose the graded benefit design, they would be more likely to be satisfied with it.

Panelists also discussed whether people should be encouraged to choose the plan by rewards or face penalties if they did not. A number of panelists suggested that penalties are more effective than rewards. For example, one

panelist said that the literature was clear that if you raise co-pays for drugs, utilization will decrease; but reducing co-payments for drugs does not necessarily increase utilization at a comparable rate. People have many reasons besides cost for not being adherent to their therapies. So you get some increased utilization, but mostly the people who were already adherent pay less.

One example we hear was one plan that provided incentives for their members to fill out risk assessments, and they got a 30-percent participation rate. Then they put a surcharge on premiums if the members didn't do the risk assessment. At that point participation increased to over 70 percent and was still increasing at the time of our discussion. A number of panelists suggested that actually you need a combination of rewards and penalties.

Some panelists thought that beneficiaries should have a choice of benefit designs each year during open season. But others pointed out the risk of adverse selection if people were free to choose each year.

Panelists suggested that benefit design change must involve beneficiaries and providers at each stage of the process. They agreed that convincing beneficiaries of

the advantages of a new benefit design would not be easy. One panelist noted that Americans tend to think that higher costs mean services are better. Interestingly, several panelists suggested that their research with consumers found that use of the term "value" implied cheap and lower quality.

Consumers are also worried about the possibility of being denied needed care. Others noted that although this is what the public says, when actually given a choice they, again, to quote one panelist, "vote with their pocketbooks." For example, another person noted that when given the choice among employer-provided drug plans, most employees chose plans with lower premiums even with tighter medical management. Enrollment moved to those plans over time and satisfaction remained high.

They suggested also that benefit design has to be comprehensible to the public if they are going to accept it. The public has to know how they would benefit from a change. Some people also commented that there is just not enough attention given to the risks of receiving low-value services. For example, again, the example that kept coming up was that the public should be educated about the risks of

overexposure to excess radiation with unnecessary imaging.

As I mentioned at the beginning of this presentation, panelists agreed that reforming benefit design using variable cost sharing to encourage the use of high-value services and discourage the use of low-value services is an important task. This slide summarizes some of the issues raised in their deliberations that you might want to discuss.

First, at what level would you center variable cost-sharing? Should it be at the level of the individual service, the provider, or the plan? Or perhaps a combination of these approaches?

The panelists agreed that beneficiary choice was important but also suggested different ways in which this could be achieved. For example, here again the opt-in or opt-out model, the one-time choice, or an annual open season.

What do you think about integrating medical management into benefit design? For example, again one plan raises cost sharing based on precertification for advanced imaging -- or actually lowers it if advanced imaging is certified.

How would you structure beneficiary incentives to get them to choose this benefit? Would it be penalties? Would it be rewards? Would it be a combination of both?

And what do you think about the location for decisionmaking? For example, should priority setting be done on a local or national level?

Of course, I will be happy to answer any questions and any suggestions you may have for future work in this area.

MR. HACKBARTH: Thank you, Joan. It sounds like that was a fascinating discussion.

Mark, do you want to just say a little bit about the context of this work and how it fits into the longer plan?

DR. MARK MILLER: All right. And I think this last slide here will help do that.

As Joan said, we wanted to get in front of you quickly on this, perhaps even a little bit out of sequence, because there were a lot of interesting things, and even just one-off things, you know, the opt-in and the opt-out, positive and negative incentives, how you can engage the beneficiaries, stuff that applies much more broadly and, as

Joan mentioned, even to the conversation today.

But the reason we were having this -- and I think this will flow into this slide, and this is for the public's benefit as well as Commissioners. You know, for many years, MedPAC has been focused on the incentive structure in the provider community and, you know, trying to align incentives between institutional providers, physicians, nurses, that type of thing. But then there's also this other really important actor involved in consumption of health care -- the beneficiary -- and looking at that incentive structure, and we've had a couple chapters now on looking at the benefit design of Medicare. So that's kind of the macro we're trying to bring alignment in those incentives. And I was just writing down things to summarize, but I think a lot of it is captured here.

When you think of benefit design, what level do you want to think about? And these aren't necessarily mutually exclusive, but many people come to this debate at the service level and say we can begin to incent co-payments, or just for example, service by service based on their value, patient by patient. And other people believe that that process is very fraught and very difficult and

evidence is -- and so begin to start to think about it other ways, through networks of providers, through coupling, and this will be surprise to you, Mitra, management integrated into the benefit design, something that Mitra has said many times -- and this came out in the discussion -- or choosing plans, making the choice at that level, that type of decision.

And then I think the design features underneath are just some of the permutations underneath it. But I thought that the levels here was a good way to think about as we approach benefit design, thinking about it in some of these categories would be a helpful way to consume some of this information.

MR. HACKBARTH: Okay. We've got roughly a half-hour, and so I'd urge people to keep that in mind as they frame their questions and comments.

I think it would be useful to do a fast round of just clarifying questions only, if there are any of that nature. Actually, we're starting on this side this time.

DR. STUART: I guess I'm not surprised that there was kind of pushback on the use of the term "value." We all think that way. We've got the Value Dollar Store. So did

the participants have any way to get over that semantic issue?

DR. SOKOLOVSKY: That's where the idea of the graded benefit came from. I mean specifically by someone who had done this research and said we want to sell this, we can't sell it this way, what about if we talked about a graded benefit. And that is what they are offering.

DR. STUART: Would that constitute then a different -- you know, kind of the platinum, gold, bronze, but we'd flip them upside down?

[Laughter.]

DR. KANE: It seems that the comments are in the context of the historic Medicare program, and I'm wondering, for instance, the level of value assessment. You have the word "plan." Aren't we talking about how to get value-based purchasing into the fee-for-service? And do we bring in the notion -- when they were doing this discussion, did we bring in the notion of maybe ACO, you know, whether you could bring in value-based purchasing on whether they opt in or out of an ACO or some of the more futuristic types of what Medicare might look like, and also the whole notion that we will have this, you know, clinical effectiveness type of

process going on? So was this context largely historic, or was there some kind of consideration of what we hope is happening in the next five years?

DR. SOKOLOVSKY: Frequently, people would mention the importance of the comparative effectiveness research that's going on now, but they didn't think that it was necessary to wait until all that information was out there. They thought there was enough information out there now to at least begin this process.

In terms of ACOs, they didn't actually use that term, but they knew we were talking about fee-for-service Medicare, and that's kind of what I heard in my head. But I never heard the expression.

DR. KANE: Because the word "plan" up there isn't meaningful, until you use -- unless you -- go ahead.

MR. HACKBARTH: Although one of the options that Joan said was discussed was having different plan options within Medicare so you could give people, you know, Plan A versus Plan B, and it could be an option available at any time, or it could be done for new beneficiaries after some date. So plain could be introduced, different flavors of Medicare.

DR. KANE: So ACO would be provider level? Or would it be plan level?

DR. MARK MILLER: I mean, the way I would try and answer this is -- and on the plan point, just to reinforce that, just in case anybody missed it, it's sort of the notion of right now you have traditional fee-for-service and a managed care plan. What if there was a choice that you had a more graded or managed plan that somewhere stood between and that was reflected in your premiums and co-payments? And in a sense, you don't try and go down and manage each and every service. You say you can pick a plan that has more management or a plan that has less, and your premiums and co-payments will reflect that. And that is at a very plan level, but it is still fee-for-service, just a different kind. You might have networks and that type of thing within it.

I would say the provider stuff are things like the notion of saying, you know, there may be networks where groups of providers who are operating -- more of the ACO concept, operating and certainly following clinical pathways, that type of thing. If you use those providers, your co-payments are different, or whatever mechanism you

are, to try and incent them.

DR. KANE: So who would provide the medical management in a plan variation off either Medicare fee-for-service or MA?

DR. MARK MILLER: I think that's a big, giant question. I mean --

DR. KANE: Okay. I'm not -- all right.

MR. HACKBARTH: Okay. Any more clarifying questions?

MS. BEHROOZI: [Off microphone] oh, there it goes. Would Medicare Select be the kind of model that you're talking about then where it's really run by Medicare, it's not an MA plan?

DR. MARK MILLER: I mean, I think that's her question which we just tried to avoid, but --

[Laughter.]

MS. BEHROOZI: [Off microphone] Did you mention Medicare Select?

DR. MARK MILLER: Medicare Select is an ideal like that where it's kind of a modified fee-for-service. But just to say one word about this, I mean, is it a private option or is it a Medicare-run option if you had this more

managed fee-for-service. That's the question.

MR. GEORGE MILLER: I apologize. I have got one because I want to follow up on Mark. From your perspective, the overall goal, what you just described in response to Nancy, is the overall goal to give this as one choice? Or is this the ultimate goal to try to move everyone into this type of a plan for the entire program?

DR. MARK MILLER: My "goal" would be way too big of a word. My statement for this conversation is a thread of the Commission's work is looking at benefit redesign. It could take many forms, and I was trying to put them into categories for you to kind of consume the comments of the panel in a structured way.

MR. HACKBARTH: So let's keep in mind what this way. We invited some outside people to share their experience and perspectives. On this particular issue, at least some of them said that it's best to do these things giving beneficiaries/patients a choice, that it goes down easier if there are choices to be made as opposed to you're forcing everybody into something new. Did I hear that correctly, Joan?

DR. SOKOLOVSKY: That was actually something that

nobody disagreed with.

MS. HANSEN: On page 9, the graded benefit consideration that we're talking about, was there any discussion about what this would mean for types of beneficiaries who would be dual eligibles? Because this implies, you know, full choice with kind of the co-payment premium. But in the case of oftentimes the dual eligible, that would not be a factor. So how could we guide that direction for the more effective use of resources?

DR. SOKOLOVSKY: I think there was no specific discussion of dual eligibles except for the note that without medical management this would not be practical for lower-income beneficiaries in particular.

MR. HACKBARTH: Okay. Round two comments?

DR. BORMAN: I think that, again, the richness of this presentation maybe has a message for us that in these particular ways, wherever we choose to use them -- and I think Mark's framing of them was very helpful -- we periodically need to do this biopsy because this kind of stuff is about behavioral modification, and this kind of biopsy and the kinds of insights that Joan typically brings us about this I think will be very helpful in this. And it

shouldn't be just an isolated thing that we do.

DR. DEAN: Just a note of caution. I think you already mentioned it, Joan. I would be real nervous about trying to assign value in a broad sense to any individual service, because there is so much flexibility and so much idiosyncrasy related to each individual clinical situation that things are -- I think it would just be fraught with problems.

One other thing that struck me, and I don't know if it's directly on the point, but the idea of assigning value based on whether something is certified for a particular condition is also fraught with value -- fraught with problems, not value. And the one that has driven me crazy lately, there's an old, old drug named colchicine, which was the standard treatment for gout for many years. It's so old that it had never been through the FDA process, and so all of a sudden the FDA in their wisdom decided to run it through the process, and the price went from about 10 cents a pill to $5 a pill. And, you know, that's -- so what does that do to the value?

MR. ARMSTRONG: Yes, I just wanted to add that in our experience, in my experience, there are a lot of

organizations experimenting with what are being labeled as value-based benefit designs. I know we are doing a lot with big, 15,000, 20,000 member groups. Our own employee group happens to be one that we're working on. You know, zero co-pays for those things you want people to get a lot of, and as much evidence applied to other kinds of benefit structures, incentives for health risk assessment, you know, things like that.

And so as we continue our consideration of this, I assume we will look at the evidence that is beginning to come out of what are pilots taking place all around the country.

DR. CASTELLANOS: Just Slide 11 for a second. First of all, I thought it was an interesting presentation. I looked at the panel that you had, and they really are really good experts. Again, I'm coming from a very practical experience. I think you need to get beneficiaries and providers engaged in this, but you need to get some people who are delivering these services and people who are receiving these services and get their input, too. I'm not saying the panel wasn't good. I'm just saying you may get a different approach by getting some providers and

beneficiaries.

MS. BEHROOZI: I know we're limited on time, and I think Joan and a few other people know that Joan and I could talk about this for a very long time together, so I won't do that. And she already said twice, you know, one of the highlight comments about lower-income beneficiaries and management.

But I also think that what you said, Joan, about increasing co-payments reduces use more than reducing co-payments increases use, I think that's a significant item. I haven't seen that literature that you said that somebody on the panel cited, and I'd love to see some of that because, you know, I'm coming from a world where have not ever had co-payments. So we are only looking at the possibility of raising them because costs are getting out of hand and not because we think that it's going to more effectively manage, but because the employers are not willing to continue bearing the ever escalating costs. So w see it as a cost shifting, and we are worried about the implications, and, you know, I've raised that many times before about the possibility, likelihood of there being as much appropriate care that gets avoided as inappropriate

care, or maybe even more so. So I'd be interested in seeing some of that literature.

The reason that I asked about the Medicare Select program, because, you know, I learned about that here, I guess principally in Rachel's work, and it does seem like it's important for the Medicare program to position itself to be able to reap some of the savings, some of the opportunities for higher-value care by kind of putting itself in the position of the plan. I know that Medicare Advantage has brought a lot of improvement for a lot of beneficiaries, but, you know, whether the program has been reaping the benefits -- I guess not if we're paying 16 cents more for every dollar worth of benefit that beneficiaries are getting.

So it does seem to me that it would be good, whether as an experiment or going forward forever to have the program have an alternative, like an expanded version of Medicare Select. And I think that it could be a good thing to do it that way because you could leave fee-for-service intact. You wouldn't have to deal with all the statutory requirements about choice and things like that. But you would use lower cost sharing to incent people not just to

manage them by the cost sharing but into a more managed system. And it's really the management that will bring you the higher quality at the lower cost because then you can have people in a system where costs are not a barrier to receiving quality care, and you can really be on top of that in a very direct way. So I would vote for that.

DR. CHERNEW: So it's not surprising that I'm thrilled that you're doing this, and I think it relates to a much broader question that we've taken up with increasing frequency lately, which is what the role of beneficiaries is in the Medicare program as opposed to just how we pay, and I think in general that's good.

My main point I want to make is it's important when we go through this not to think that the -- not to let the perfect be the enemy of the good. It's very easy to go through a whole series of places where this won't work, it can't work, it will be bad to work, you couldn't extend it to work. But when all is said and done, figuring out where it can't work doesn't seem to be like the real issue. The real issue seems to be figuring out where it can work. And although I recognize that there's a lot of ways in which it's hard, in fact, in a whole number of areas, we're there

anyway one way or another. The coverage determination process, which tends to be service by service, is an extreme version of you get full coverage versus no coverage. And things we've talked about, evidence development and all, are examples of where in a service level one might try and do this and that matters.

We're in the process of redesigning -- we aren't, but someone is in the process of redesigning the Medigap programs for C and F, so that's going to change beneficiary incentives. It's important to think through whether we care about that or not or what the clinical ramifications of that are. And this type of stuff could matter.

The least costly alternative discussion that we're about to have is exactly this, and much of the chapter is, again, on a service-by-service thing, although one could think about it on a panel-by-panel thing. In the bill, the reform bill, PPACA, there is the carving out of services that are Grade A or B from the U.S. Preventive Services Task Force. So there's an enormous number of ways in which we don't really have a choice we're going to get there. And I think in the private sector there's an enormous amount of venture capital and incredibly energetic activities. Every

plan that I know -- Scott mentioned theirs -- is trying some variant of some way to combine the supply side payment stuff with the demand side incentive things. And I think it's easy to think of reasons why -- well, people don't like the word "value," which I'm fine with them not liking. But that sounds to me like the fifth order concern that we have beyond the basic notion of we got to be careful we don't charge people too much for things that we really want them to get, and we don't want to make everything free that we want them not to get, particularly if you put them in ACOs and then the ACOs ask to have some benefit design.

So this is my long way of saying I think this is a great step, and I look forward to seeing what you're doing. And I think as we move forward to take this into account, it will just have to be done on a case-by-case sort of small area. But I do think in the end it will prove very fruitful.

DR. NAYLOR: Very briefly. I find this very exciting to think about a path to engage beneficiaries in benefit design, and it seems to me the path toward getting toward a different kind of benefit program, you know, trying to direct people toward tiered, more efficient providers

will require us not just to look at top cost items within the Medicare program, but a cluster of costs over episodes of care for people. And it will also, I think, help us to confront some of the barriers, because local communities know who efficient providers are, but people right now have choice, beneficiaries have choice to go to the home care agencies or long-term care agencies or others that they want to go to.

And so even though we may know a path toward higher-quality, more effective, more efficient -- not value -- care, right now we have some barriers in play that make it more difficult for us to guide consumers toward the best, more efficient providers.

MR. HACKBARTH: Any others?

DR. KANE: I think it would be also useful in thinking about this where the best -- at what level would this best be implemented, so national or by the inter -- I mean, sort of this whole is, is it a plan, is it an ACO? Do you want the providers thinking about how to manage the benefits -- I mean, the value base in the design?

I'm still having trouble thinking for the fee-for-service population who would take responsibility and have

the internal capacity to implement for the fee-for-service. And so it would be just nice to have that as one of the things that we explore in the future.

DR. DEAN: Just a quick response. I made the comment that I didn't think that each service should be evaluated individually. At the same time, I thoroughly accept what Mike just said, that things like coverage with evidence development is a tremendously valuable process, and we really should be doing that a lot more. So I don't know; maybe I'm on both sides of the issue. I don't know.

[Laughter.]

DR. CHERNEW: I think this issue of who makes these determinations is like the prescription drug stuff has done a lot, but Part D is a hard place to do this because we've pushed those decisions down to other entities. So figuring out the process by which this happens, which you've discussed in your panel, I think is going to become really important. But I think avoiding it is going to be [off microphone] hard.

DR. BERENSON: I wanted to join this discussion about the individual service. Mark, you said that the coverage decision is sort of an all or nothing the way it

works now. And yet virtually every decision is called coverage with conditions, which is supposed to make it very specific to an individual diagnosis, circumstances. And I think that partly is -- I mean, in fact, we are thinking we are doing that now, bringing sort of nuance, that if you don't -- if your QRS interval was not such and such, you don't get to use the new device. But if it -- I wonder how well that works.

It is clear that there's no -- it's very rare to get a yes or no on a coverage decision now. It's always very clinically specific. And I just wonder how well it works.

DR. CHERNEW: I didn't mean all or nothing in that sense. I mean all or nothing, it's covered so it's paid for, or it's not covered so it's not paid for, as opposed to, well, you know, we're going to cover this, but if you want access to it -- like the least costly alternative version of this would be we'll cover it, but it's -- we'll pay up to the least costly alternative as opposed to you pay all or nothing. That's what I mean by the all or nothing.

DR. BERENSON: My point is that we are sort of -- in the coverage process, we are thinking we're bringing

clinical nuance to those decisions, which we would have to do in any approach, as Tom says. I mean, the idea -- every service, it varies based on the circumstances as to whether something is value or not. And, you know, if we're going down this road, I'm sort of curious to see to what extent we are able to operationalize those conditions, that, in fact, we are getting coverage for the specified conditions and not for the others. I mean, are we able to sort of control all that?

MR. HACKBARTH: Okay. Well, thank you, Joan. Good work.

We'll now have a brief public comment period.

[No response.]

MR. HACKBARTH: Hearing none, we are going to lunch, and we will reconvene at one o'clock.

[Whereupon, at 12:02 p.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION [1:04 p.m.]

MR. HACKBARTH: Okay. First up this afternoon is "Clarifying Medicare's authority to apply least costly alternative policies."

Nancy.

MS. RAY: Good afternoon, everyone. I'm here today to follow up on our discussion from last month on least costly alternative payment policies. First, I will review some material on the background and Medicare's application of these policies that we went over a bit last month, and then based on your discussion from last month I will present two draft recommendations that are about giving the Secretary clear legal foundation to apply these policies.

Under least costly alternative policies, payment for a group of clinically similar services is based on the least costly item. Least costly alternative policies do not require new or additional collection of pricing data. Medicare uses its existing statutory payment formulas to set the payment rate. When applying least costly alternative policies, it is necessary to assess the evidence on whether a service is clinically similar to another service. By

setting the payment rate based on the least costly item, these policies have improved payment accuracy. This has, in turn, reduced beneficiary cost-sharing as well as spending for taxpayers and the program.

Since the mid-1990s, Medicare's contractors have applied least costly alternative policies locally in their geographic jurisdiction for durable medical equipment items and Part B drugs. In one instance, CMS implemented a LCA type of policy nationally to pay for two biologics under the Hospital Outpatient Prospective Payment System. This was in 2003.

We anticipate that opportunities to apply least costly alternative policies will increase. For example, there is head-to-head clinical trials going on right now that are in the pipeline, and once those studies are completed they may be useful in informing least costly alternative policies.

Medicare has applied these policies based on the statute's provision that no payment may be made for any expense that is not reasonable and necessary for the diagnosis or treatment of an illness or injury. Around 2008, a beneficiary challenged the use of these policies to

pay for a Part B inhalation drug. The Federal Court agreed with the plaintiff, the beneficiary, and said that Medicare must follow the detailed statute in setting the payment rate for the Part B inhalation drug, the average sales price. The Secretary appealed this decision, and the appeal to the Federal Appeals Court also agreed with the plaintiff. As a result, in April 2010, the least costly alternative policies have been removed for Part B drugs.

So to summarize then, least costly alternative policies are an important tool to improve price accuracy and increase the value of Medicare spending. As a result of the two Federal Court decisions, the Secretary's current authority to apply them is uncertain.

Considering these points and based on your discussion from last month, here's the first draft recommendation: The Congress should give the Secretary the authority to apply least costly alternative policies in setting payments for items and services covered under Medicare Parts A and B. The Secretary should periodically assess the clinical similarity of Medicare coverage services and apply least costly alternative policies for those services deemed clinically similar.

This draft recommendation is designed to provide the Secretary a clear legal foundation to apply least costly alternative policies. We are waiting for additional scoring information from CBO. We expect that it would decrease spending relative to current law. This recommendation, we expect, would decrease beneficiary cost-sharing in the short term and premiums in the long term. We don't anticipate that it would have an effect on access to care. It might decrease providers' revenues.

This draft recommendation includes a requirement that the program evaluate opportunities for its application. You might want to consider this option because in the past CMS has not always been able to use a new flexibility. For example, Medicare has an important pricing authority called inherent reasonableness that it has not exercised, even with the OIG's recommendations.

Using this clear statutory authority, CMS would need to develop a systematic process to consider and implement least costly alternative policies. Characteristics of this process include it being clear and transparent, identifying and defining groups of clinically similar services, permitting opportunities for public input

and comment from a wide range of stakeholders, including obtaining clinical, technical, non-binding advice from an advisory group, including the opportunity for medical exceptions based on the requirement of medical necessity, and I'll talk about this in an upcoming slide, a little bit more.

And it would also need to include the opportunity to permit beneficiaries to choose the more costly item, even if providers do not see a medical reason for it. The beneficiaries' liability would include the 20 percent co-insurance of the least costly alternative item plus the difference in the Medicare payment between the more costly and the least costly service.

Establishing this clear and transparent process would ensure that this new flexibility would not impede upon beneficiary access to needed care.

So I presented this slide at last month's meeting, and I just want to review this information again. There are several different ways to set up the process for implementing these policies. The Secretary could be given some discretion in setting up the process or the statute could lay it out.

And I'm just going to go over some of the advantages and disadvantages, some of the different options for setting up the process.

Least costly alternative policies could continue to be applied locally by Medicare's contractors, nationally by CMS or both. Advocates of the local process contend that it is quicker and it is a more flexible process. On the other hand, national implementation would provide for consistent policies across geographic areas. There is precedent for giving the Secretary the authority to implement the policy both on a local basis by contractor and on a national basis by CMS, and that precedent is the inherent reasonableness policy.

Other options for implementing least costly alternative is to continue to do so through the coverage process which has a process for obtaining stakeholder comment on draft policies. It's important to note that most coverage policies do go through the local process. The national coverage process usually deals with anywhere from 20 to 30 determinations per year.

On the national coverage side, there is the MEDCAC, a clinical advisory group that offers non-binding

advice. There are some issues in how the MEDCAC is organized, and that might have to be addressed if it was used in the LCA process.

Alternatively, Medicare could implement least costly alternative policies through the payment process. Inherent reasonableness is under the payment process, and CMS has some experience in considering the clinical contribution of a service or item in the Hospital Inpatient and Outpatient Prospective Payment Systems.

So to summarize here, there are different ways to set up the process for least costly alternative policies which the statute could lay out or leave up to the Secretary's discretion.

Now I want to pause, stop here for a moment, and Glenn made four points at the September meeting, and I'd like to take this opportunity to address each of these points. I'd also like to acknowledge that applying least costly alternative policies is not without controversy. Some stakeholders argue that Medicare should not be applying them, and they come in arguing some of these four points. On the other hand, some stakeholders argue that least costly alternatives are an important tool to increase the value of

Medicare spending by shifting utilization from the more costly item to the least costly item.

The first two items, the transparency and the beneficiaries' access to care, are issues that the Secretary would have direct jurisdiction over. The latter two issues are broader -- the effect of these policies on market pricing and on manufacturers' incentive to innovate. I think these are a bit more ambiguous.

So the first issue is that least costly alternative decisions may be made poorly. However, as we discussed in the previous slide, the Secretary would need to develop an open and transparent process in which to apply them. The Secretary would need to solicit a wide range of stakeholder input, including from beneficiaries, providers and other stakeholders.

The second issue is that these policies would interfere with beneficiaries' ability to access care. Least costly alternative policies are not intended to impede beneficiaries' access to care. And, as discussed previously, it would be necessary in this clear and transparent process for the Secretary to establish a method that would ensure Medicare payment of the more costly item

or service when the clinician justifies that it is the single best clinically appropriate course of treatment for the beneficiary. A process could be established that would permit clinicians the opportunity to submit requests for exceptions to, for example, Medicare's contractors who would then respond to the request based on reviewing information about the patient's medical condition and the evidence in the medical literature.

So now let's move to the last two bullet points where there's a little bit more back and forth here.

The third issue is that least costly alternative policies are an intrusion in market pricing. However, most policy analysts agree that a properly functioning market economy does not exist for the delivery of health care goods and services. Compared to other markets, the health care market is not as functional and does not foster price competition for a number of reasons including lack of good information on pricing and comparative clinical effectiveness. Another contributing factor is the price insensitivity of individuals with third party insurance.

The fourth and final question is the effect of least costly alternative policies on manufacturers'

incentives to innovate. This last issue is of particular concern to many product developers of new products. They have argued that pricing policies applied to on-patent products decrease manufacturers' ability to recoup the cost of research and development, which in turn negate the effect of patents and undermine the incentives for product improvement or product development. They also contend, argue that product developers might shift their research towards diseases not currently treated by multiple approaches or reduce investment in products that are incremental improvements of other products.

On the other hand, proponents of reference pricing policies, or more generally evidence-based payment policies, counter that such policies might increase manufacturers' incentive to develop more innovative products and to compare their product with other products in the clinical trials they sponsor. Proponents argue that paying more for better results is the best way to spur the kind of innovation desired most by patients, clinicians and payers.

Determining the impact of any health care policy on the pace of innovation is difficult for a number of reasons. The socially optimal level of research and

development is unknown. Many factors, both health and non-health related affect manufacturers' decisions to invest in R&D.

So to conclude on this last issue, the effect of least costly alternative policies on innovation is ambiguous. I leave it for Commissioners to consider both sides of the argument in your deliberations.

During the September meeting, an issue was raised about setting the payment rate of a new service. In many instances, payment for a new service is more than existing options, even though it has no evidence showing it results in superior clinical effectiveness than existing options. Two of Medicare's existing payment methods on the hospital side have a mechanism to pay more for a new service or device that results in better outcomes, but we don't have the opposite policy; that is, that sets the payment rate of a new service without clinical evidence at a rate that is no higher than existing treatment options.

This leads us to Draft Recommendation 2 which is designed to address this issue, and it reads: The Congress should direct the Secretary to set the payment rate for a newly covered service that lacks evidence, demonstrating

better outcomes than existing treatment options, at a level that is no higher than the least costly alternative.

At this point, we believe the same effects that we described for Draft Recommendation 1 would apply. CBO is still looking at this.

To implement this draft recommendation, the Secretary would need to establish payment rates for new services under a clear and transparent process. That again, of course, provides opportunities for comment from a wide array of stakeholders. As discussed earlier, CMS has already some experience under the Inpatient and Outpatient Hospital Payment Systems in developing the process and assessing whether new services represent clinical improvements compared to existing treatments.

So I'd like to conclude here and summarize that least costly alternative policies have improved payment accuracy and resulted in savings for beneficiaries and taxpayers. Medicare's legal foundation to apply them is unclear. Having a flexibility established is important; future opportunities these policies will likely increase over time. We seek comments about the two draft recommendations that would give the Secretary the authority

to apply least costly alternative policies, and to develop a clear and transparent process to implement them.

MR. HACKBARTH: Okay. Thank you, Nancy.

So we do have a couple of draft recommendations here. There will be no votes today, for people in the audience. These are for discussion, and then based on that discussion we will decide on final recommendations to be voted on at a later date.

So let's begin with a first round of clarifying questions, beginning with Mary.

DR. NAYLOR: Thank you for a terrific and balanced review of the policies.

On the issue about national implementation of least costly alternative policies, I think you said it's used annually in 20 or 30 cases. Can you give examples of situations in which this has been used or applied nationally?

MS. RAY: Let me clarify. Up until this point, Medicare has implemented least costly alternative policies on a local basis, in the local coverage process. When I said that there were 20 to 30 national coverage policies, those are like policies for covering ICDs and other

services. The national coverage policies, up until, have not applied least costly policies, to be clear.

DR. MARK MILLER: Right. The reason that you were bringing that up is because what she was talking through is potential processes within the agency past that an LCA type of process could follow, and that's why she was mentioning the 20 NCD decisions, right?

MS. RAY: Right. I think some stakeholders have raised the issue: Well, if you were to think about putting this process in a national coverage area, that may need to be retooled because right now it really is only designed to be considering 20 to 30 determinations a year.

DR. MARK MILLER: I'm sorry, and I couldn't rattle them off for you, but there are local LCA decisions, and we can get you examples of those.

DR. CHERNEW: This is a question about Recommendation 1, although the term I'm going to ask about appears throughout the text, in a number of different contexts, which is: Is there somewhere a definition of "clinically similar?" You mentioned deemed some things "clinically similar."

MS. RAY: You're right. I mean I guess our

briefing paper doesn't explicitly define it. I think "clinically similar" would, I think, be two or more items having, or that they have comparative clinical effectiveness. They produce similar outcomes and side effects.

Or, just to give you another way to look at it, that a service does not show that it produces better outcomes than existing treatment options.

So I would pin it on the outcomes and side effects of a service.

MR. HACKBARTH: As a practical matter, it's not a bright red line sort of standard. It's going to entail judgment informed by expert opinion.

DR. CHERNEW: I'll save that for another round. I was just wondering if there was something I was missing, if there is some like officially defined answer to that.

MR. BUTLER: So I read in the material that the statutory provision that we currently live under, which is gray, it kind of doesn't give specific guidance to LCA. So I hate to get into legal things, but my guess is that you've thought about if not specific language, you feel fairly confident because of this recommendation that language could

be created that would not be subject to too much challenge in court. That's what we're trying do anyway, and we're pretty confident that that can be done.

MS. RAY: Yes.

MS. UCCELLO: I have a question with respect to the local contractor process. How much are these decisions made in isolation from all the other areas, or do they leverage findings from other areas?

MR. HACKBARTH: When you say "other areas" you mean other localities?

MS. UCCELLO: Other localities, yes.

MS. RAY: That's a good question. For the durable medical equipment items, there are four contractors, four local contractors who administer those claims. They each publish policies, but the policies have to be consistent from contractor to contractor.

For the, I think, 15 Part A/B contractors, that's where there can be variation. However, there is, to my understanding, interaction among the medical directors in the development of local coverage determinations. And in fact I recall one of the CMS manuals encouraging that collaboration among contractors.

And I think also with contractor reform, now that we have only 15 A/B contractors, I guess it may make it easier to collaborate and maybe decrease variation.

DR. MARK MILLER: But it is also true that you can end up with different policies from area to area, and I've heard arguments on both sides of this, even from the industry. So the industry can come in and be upset that there's an LCA in one area and not in another. But by the same token, I've heard the industry argue that one of the reasons they like the local process is they can get an innovator in one area, then use that information to disseminate and then even maybe call for a national coverage decision. This local/national is kind of an interesting distinction, and pluses and minuses in either configuration.

DR. CASTELLANOS: Slide 10, Recommendation Draft 2, I just think you need to clarify a little bit better who is going to make the decision that that service lacks evidence -- in other words, any new coverage service that lacks evidence demonstrating better outcomes. I think you kind of need to clarify who is going to make that decision.

Do you understand my point, because you're going to have a lot of controversy about saying this is better

than this? My toothbrush is better than your toothbrush. Somebody has to be a final decision-maker. You're going to have to outline how you're going to look at that evidence.

MR. HACKBARTH: We can come back to this in the second round, Ron. This is an important area, but the general idea is to establish a process that's transparent and engages expert opinion in advising the Secretary on issues like this.

DR. CASTELLANOS: Is that clarified here? I don't see it clarified here.

MR. HACKBARTH: Well, as I said, we can come back to it.

DR. CASTELLANOS: Okay.

MR. HACKBARTH: Maybe we'd need to modify the language of a recommendation.

Nancy, is there something you want?

MS. RAY: I just wanted to add that in the two instances where Medicare already does set a higher payment for a new service that shows that it's better than others, than existing options, that process has been set up in the Inpatient and Outpatient Prospective Payment Systems. I think it's usually done through the rulemaking process.

DR. CASTELLANOS: Public hearing, et cetera. But I think that needs to be clarified.

DR. BERENSON: I want to also talk about that definition. I mean lacks evidence could mean there might be an absence of evidence, or it could be there is evidence which shows no better outcomes.

This language would suggest even in the absence of any evidence the Secretary would not be paying more. Is that the intent?

DR. MARK MILLER: We took the comment from the last meeting as that being the intent, that the burden of proof in a sense would --

DR. BERENSON: Well, I'll reserve my comments for round two then. Okay.

DR. KANE: I have three questions, but anyway bear with me.

The first one is you talked about inherent reasonableness being an authority that CMS already has, but doesn't use, and I'm wondering why not. I mean is there a short answer to that, or is there a very long one?

MS. RAY: I think there is, because CMS has to go out and collect pricing data, and that pricing data have to

be nationally representative and so forth and so on. So I think the burden there is shifted entirely on the agency to show that a payment is either too high or too low.

DR. KANE: So this pushes the evidence burden onto the provider?

MS. RAY: Right.

MR. HACKBARTH: Correct me if I'm wrong, Nancy, but on this particular issue of where the price comes from, here you've got a service that determined to be clinically similar and a price for that already existing as opposed to under inherent reasonableness where they're going out and having to gather price information. Is that accurate?

MS. RAY: That's perfect.

DR. KANE: Okay. So the second question is the word "service." I know we talked about drugs, and we've talked about devices. But is the intent to make this applicable to more than those two classes of services?

DR. MARK MILLER: Yes. I mean I think our expectation is certainly in the near term like the policy when it was in place. It's likely to be drugs and devices in the short term because those are usually more clear. You can run head-to-head types of comparisons.

But the question is if you're going to ask for this authority whether you want to at least allow for the future, for it to be broader than that. But certainly I think the expectation is in the near term it's probably drugs and devices, but it is "service" to leave it open-ended.

DR. KANE: So you want to leave it. You think it would be better to leave it open-ended?

DR. MARK MILLER: That's a choice.

DR. KANE: Okay. Well, we can come back to that.

My last question is I think on Slide 8 where you're talking about market pricing. I understood you to explain why there is no market, but I didn't hear any explanation of what we know about how manufacturers behave to set prices in a reference type or an LCA type market. In other countries or here, do we know kind of what the pricing behavior is, whether or not the market is working in terms of transparency and things?

In other words, might a manufacturer say well, if there's going to be LCA, I'm going to not introduce something that might be a lower cost because my other products will come down, or those kinds of things. Do we

know anything about how manufacturers behave in that environment?

MS. RAY: Pulling an example that I think I included in your briefing, from your briefing, there was the case of Medicare applying reference pricing in the mid-1990s to 2 specific products used for prostate cancer, and that was in the mid-1990s. And subsequently, newer agents were introduced and remained on the market. So at least I don't think in that instance.

I think also, and correct me if I'm wrong, Joan, but I think under the last costly alternative policies the pricing for those products has decreased.

DR. SOKOLOVSKY: As new products came into the market they came in actually at lower levels. This was originally for two drugs, the newer. But before this policy was withdrawn in April, the least costly alternative was also the newest product coming into the market. Since the policy has been withdrawn, we have seen price increases for the other products.

DR. KANE: I think my question is a little different, but I read that part. So, in countries where they have reference pricing, are prices generally lower or

higher than here? In other words, how does it more broadly affect pricing overall, not just for the new?

MS. RAY: I think internationally what the literature has concluded, that is overall prices are lower. And I think that's because of the reference pricing, and there are two kinds of reference pricing that are used internationally. One is reference pricing within a country, and then at the same time certain countries actually not only use reference pricing in the country but also make sure it's known that it's lower than other countries as well. So there is sort of the internal and external, and I don't think those are the right terms for it, but referencing pricing that is used internationally.

MR. HACKBARTH: Just for the sake of clarity, let me ask even a more basic question. So somebody comes in with a new drug. There's no LCA policy in effect, and they say this is new. How does Medicare set its price for that new item?

MS. RAY: Using the statutory payment formula that is already in place.

MR. HACKBARTH: And just elaborate.

MS. RAY: Okay. So, for example, if it's a drug

and if it's a Part B drug, it would set the price based on the average sales price. All right.

MR. HACKBARTH: Right.

MS. RAY: Then when the second drug, a newer drug came into the market, the manufacturer, again that payment rate would be calculated using average sales price.

If the newer drug was clinically similar to the original product, then the payment would be set based on the least costly average sales price.

MR. HACKBARTH: And on the average sales price, when you've got a new product, where does the data on the average sales price come from if it's a new product?

DR. SOKOLOVSKY: At the beginning, before there are two quarters worth of data, it's not based on average sales price because, as you're implying, there is no average sales price. It more can be based on wholesale acquisition cost, other kinds of benchmarks that exist, until they collect the data, and then they can move it to average sales price.

MR. HACKBARTH: So, as a practical matter, is it what the manufacturer determined its price is?

MS. RAY: Yes.

MR. KUHN: And the average sales price is what's submitted by the manufacturer to CMS.

MR. HACKBARTH: Okay. Other clarifying questions? George.

MR. GEORGE MILLER: Mine is more of a technical one. It could be wordsmithing, but on Slide 5, Draft Recommendations 1 and 2, and this is an assumption on my part, but you said there may be some administrative costs. I would assume that's going to be net of the decreased cost in spending, and the administrative cost is negligible, but I don't want to make that assumption. I would assume that's the case.

MR. HACKBARTH: I'm sorry. I didn't hear the first part. You're talking about the spending, about the last sentence.

MR. GEORGE MILLER: Yes, the last sentence. So I assume it's not a huge administrative cost, and therefore the decrease in spending relative to current law would be so huge that the administrative costs would be negligible. And if that's the case, why include? Now that's wordsmithing, and if I'm wrong, then clarify.

DR. MARK MILLER: No, no, no. That's what I'll

try and clarify, and try and do it for everybody.

So the bottom two pieces on spending and impacts on beneficiary and provider, as a matter of course, whenever we put a recommendation up we try and give you some sense of the magnitude, and we often use the scoring buckets which we've used in the past. We're midstream with this. There is an expectation of savings.

What we like to acknowledge, and that's what the last sentence was about, is that this is a new process and would be a more rigorous process within the agency, and there would be administrative costs incurred. I think the expectation, I think but I don't want to speak, is that on net those administrative costs would not swamp what you would save by engaging in the process. But we also just didn't want to blow past them and not acknowledge them.

MR. GEORGE MILLER: I think, yes.

MR. HACKBARTH: So we can come back in round two.

DR. MARK MILLER: Let me just put it this way. We would expect that the dollar amount of savings would be larger than the administrative costs. If you were inside the agency, you would say this is a significant cost to us because this is a new process for us. And so, you know, the

agency would view the need for administrative resources to administer this.

MR. GEORGE MILLER: Which may not be funded or mandated -- not mandated but funded because of budget issues for the administration. And so that's --

DR. MARK MILLER: And you may want to speak to that [off microphone].

MR. GEORGE MILLER: Yeah, that's my point. Okay.

DR. BAICKER: I just want to be sure I understand the process by which something becomes the least cost alternative and the timing and how that would affect the manufacturer's choices in initial pricing. So something new come on the market; it takes a couple quarters to get an average price that's being transacted. In the interim, this new thing wouldn't be priced higher than the least cost alternative, but it could be priced lower and could be the new least cost alternative, so that when the pricing -- that's how I interpreted the recommendation to "no higher than." So a new thing, depending on somebody's judgment, could be priced lower, and then everybody's prices go down? Or does it take -- I'm trying to understand the incentives for gaming and how people are setting the initial prices

when things first go on because they know that it may have an effect on the price that all of that class of things is reimbursed at.

DR. SOKOLOVSKY: Without least costly alternative, typically the incentive is to price higher because you're saying what I think this is what I'm going to sell it for. But then in order to get people to buy it, you're likely to give them rebates at the beginning to make it more attractive. And so there will be a bigger spread between what they actually pay, which will be lower, and what the Medicare payment rate will be. And it will take two quarters for what they're actually paying to catch up and have that ASB out there.

DR. BAICKER: At that point then, it could become the least costly alternative, after the two quarters?

DR. SOKOLOVSKY: If there is a least costly alternative, yes.

DR. MARK MILLER: And it seems related, but we've had a lot of discussion on this, as you can imagine. People wanted to come in and talk to us about this. You know, there are drug companies who have products, and they're actually not necessarily the preponderance of the comments

but are interested in the least costly alternative being present because they have the low-priced product, they come in, they drive market share to them; and then when the LCA clicked off, of course, it went in the other direction. So you do see that out in the market.

DR. BORMAN: Could you just refresh me on what the boundaries are that would determine the interaction between this process and the Patient Centered Outcomes Research Institute process? Because I sort of think I've heard things that it could be useful in support of this, but there might be some legislative boundaries on it. So if you could help me understand that, that would be great.

DR. MARK MILLER: Okay. So we've had this discussion, too, and it's --

DR. BORMAN: [off microphone] I'm sorry.

DR. MARK MILLER: It was a series of career choices that I made all through --

[Laughter.]

DR. MARK MILLER: Nothing you can do about it now.

So my understanding -- and this is going to be a very -- you know, like a non-lawyer, a citizen version of this. As best as I understand the comparative

effectiveness, it says you cannot use this information for making pricing and coverage decisions in Medicare without going through a rigorous process, and I think exactly what that rigorous process is is sort of the question.

What we've tried to lay out here is a process which gets input and information that would presumably pass some test of this has been looked at, evidence has been considered, stakeholders have been consulted, and a decision has been made. But I'm not going to say that with absolute rigor, but I also want to make a different point.

I always get the example wrong, but the degenerative eye drug --

PARTICIPANT: [inaudible].

DR. MARK MILLER: Right, thank you. So as I understand it, there's currently a clinical trial being run on that, and there's two drugs with two very different prices. Presumably, if that produced an outcome, CMS would not be prohibited with an LCA policy from using that result. That's my sense of this. But, you know, there may be lawyers who have very different views. But that's a fair question, and we're struggling with it a bit ourselves.

MR. HACKBARTH: Okay. Let me just offer a couple

comments to kick off round two here. As evidenced even in round one, these are tricky issues. On the one hand, one of the strengths of our system traditionally has been its innovation in the development of new products, many of which yield value for patients, real benefits for patients. And obviously nobody wants to damage that process.

On the other hand, we've got a significant and I would say growing cost problem and a compelling need to develop policies that focus on maximizing the value we get for each dollar we spend, not just in Medicare but in health care more generally. So finding policies that help us strike an appropriate balance is the goal.

Right now, it seems to me -- and others can disagree with this -- we're pretty far away from that balance. The system has been set way towards the innovation goal as opposed to introducing appropriate cost sensitivity and enhancing value. And the discussion we just had about how the initial prices are set I think is illustrative of that.

So we have a system that says, well, ultimately the goal is that we're going to set prices based on average sales price. Implicit in that model, it seems to me, is,

well, that average sales price is somehow a market-determined price. Well, to have a real functioning market, I think you need value-focused purchasers on the other side of the table from the sellers and developers of new products. But often that doesn't exist in health care. So often these sales prices are tilted way towards promoting innovation and not towards sustainability of Medicare and other health programs for the long run. And so this discussion is about how we might advise Medicare to strike a more appropriate balance.

I think it's important to realize that this is just a piece of that conversation, different paths by which one might choose to strike a new balance between innovation and cost, if you'll allow me that oversimplification.

One approach is to say, well, you know, we need to engage patients in making these tradeoffs, and obviously one mechanism for doing that is to increase patient cost sharing so they're not completely insulated from the cost issue by virtue of insurance. And along those lines, you know, there are lots of different ways that might be accomplished, but one example widely discussed is, you know, high-deductible health plans that make it sort of the patients need to

engage in cost-conscious choice. And there are some merits to that approach, one of which is that it's patients making the choices, patients making the tradeoffs. It's not a one-size-fits-all approach. People get to make their own judgments about what they value and how they want to spend their money.

But the rub is that that strategy only takes you so far. A very large proportion of total health care spending is on patients with serious illnesses who rapidly blow through even a high-deductible health plan and end up being fully covered by insurance. So a patient-based strategy can help, but it's not going to take you all the way. And, of course, I've glossed over the issues of how difficult these choices are for patients to make.

Sort of another strategy is to say, well, you need to engage providers in making these tradeoffs and helping us identify high value. The virtue of that, of course, is that providers more than anybody have the relevant expertise to do so, and a way to engage them is through bundling-type strategies where providers are paid not for each unit of service but for bundles of services, and then within that they can make judgments about what component parts, if you

will, they wish to buy. And that, too, is a strategy that has merit. Not only do providers have relevant expertise, but also in a provider-based system, you have some decentralization of choices. It's not one-size-fits-all. Different providers can make different judgments, and patients may gravitate towards different providers based on how those choices are made. But it also has some downsides. They can be a bit of a black box, what goes on inside the provider decisionmaking process and not particularly transparent to patients.

The last strategy and the one that we're focused on here is, well, having insurers inject more cost-consciousness into these decisions, both through the coverage process or through payment policies like LCA. This is a strategy that has some advantages. In particular, in the case of Medicare or a public insurer, you can assure a very open, transparent process with all sorts of procedural protections so that how the decisions are made is fully visible to all relevant parties and everybody gets a say in the process. So that's a real advantage.

On the other hand, because you're making the decision at the insurer level, there isn't the same variety

that you get through decentralized decisionmaking by patients or providers.

So all of these strategies have pluses and minuses. Not one is the right answer. In fact, as I look at our broad agenda, our broad work, we're doing work on each of those strategies. It's not choose one of the three, but try to get the best out of each while minimizing the disadvantages of each.

What to me is sort of non-negotiable, as it were, is that we need to develop strategies to increase the value of what we buy. The path that we are on right now, where the system is tilted way towards innovation with little consideration for the long-run cost impact, for patients, for insurers, for the public, it is simply an unsustainable system. So as difficult as these decisions are, as tricky as they are to figure out how to make them work, I don't think there really is any recourse but to try to work on each of the three tracks that I mentioned.

So that's my two cents' worth to kick off round two.

DR. NAYLOR: So I strongly support both of the recommendations proposed. I think they are entirely

consistent with our role in making sure that Medicare is producing high-quality, effective, efficient care.

I think there are tremendous strengths to the recommendations in terms of its open and transparent and systematic process, that it gives choice, that it probably will involve engagement of patients, providers, and insurance altogether.

So I have two recommendations -- tweaks, if you will -- in terms of the way that these recommendations have come forward. I do think we need to operationally define or propose some operational definitions of what a clinically similar services, products. I think we also need to spend some time thinking more about what is evidence-based, what it means when things lack evidence, and give some guidance along those lines.

I do think that there's also a role for local contractors but more engagement at the national level. So in terms of addressing in a timely fashion innovations that come on the market, maybe the local contractors can continue to play a role. But nationally I think when it comes to big-cost items, there ought to be some assessment that's going on to make sure that these are good decisions. And

maybe nationally there's an opportunity for periodic reassessment of decisions that have been made at a local level, sort of a check and balance. So you don't interrupt innovations coming into a market, but you also make sure that you have standards that apply across a nation in their implementation, especially around things that really, really cost a lot.

DR. CHERNEW: I agree with what Mary said. I'm generally supportive of what you said and of the ideas behind these things, and I think the wording in a number of ways matters. And I think the key thing is this aspect of clinical similarity. I think if you read through the chapter, for example, that talks about them working through the same clinical mechanism, so that's useful, but I wouldn't consider that's what's important. If you had a, you know, surgical versus a medical thing, I think they're very different, but they could have -- I think it's similarity of outcomes and side effects that in the end is loosely what matters more so than the mechanisms.

One thing that's odd in this case is one of the examples, which is an interesting one, has an off-label drug as the least costly alternative and an on-label drug, I

think, as the more expensive one, if I understand it correctly. And I can't imagine a scenario in which you would say, all right, we're going to make the off-label one the least costly alternative to the other one.

So, anyway, I think there are some challenges as to exactly how this interacts with the FDA, how it interacts in the process, and what really matters, I think, in our recommendation is I do think more detail on what's clinically similar and also understanding -- I like the idea of having an open process, but I'm just going to -- this is a big "if." If I were to be skeptical of the Secretary, the fact that everyone gets to say their piece might not be so soothing to me, and I might want more discretion. On the other hand, I'm worried about our ability, A, in our recommendation to define it so precisely, or then believe that that definition would make it through to the actual law. So I guess we could fiddle with the wording, but I think at this stage it's in the text of the chapter. I think we need to do a lot better job of trying to figure out what safeguards there are and describing what -- you know, for example, does clinical similarity mean it's similar, but we would apply some cost-effectiveness type thing, which is

not what I think is meant by this. I think what we really mean is basically loosely -- recognizing it's multi-dimensional, loosely equivalent outcomes, and the "loosely" part is hard. So I think that's where most of the work has to be as we go forward.

MS. HANSEN: I definitely support the direction and the content of the two recommendations. I also just want to acknowledge and appreciate the point on the implications to the beneficiary, that it's highlighted in this recommendation, that it would actually lower the potential Part B and the cost sharing in general, which is something that is significant as we're talking about when we get the least costly alternative with however the definition is operationalized and clinically similar, that there is value to all parties here. You know, I think it's awkward in the sense that it does affect the providers potentially. But if we're thinking about the whole overall lengthening of the value of the program, it's helpful both from a taxpayer standpoint as well as the beneficiary one.

I'm going to ask something that is maybe somewhat different but related to material we covered before that doesn't come probably under this category, but it seems to -

- and maybe it's too much of an outlier. But it strikes me -- and I was thinking about the area where there isn't kind of a head-to-head, and it has to do with the biologics work that we did sometime ago. At this point I think in the legislation there's a 12-year protection period before generics come into place. I just don't -- but that's an area that I think when we think about, you know, looking at this piece -- but there's a whole other piece whose share of the use of resources is going to be extraordinarily growing. And I don't know whether it's appropriate in this particular chapter, just to point out that while we're looking at this, this is somewhat tweaking at the edges when a whole other piece that doesn't have the opportunity to get evaluated, possibly for as long as 12 years, is going to affect the program in a significant way.

MR. BUTLER: So whether there's a budget issue or not, any prudent purchaser would have to endorse recommendations 1 and 2. It does kind of make sense. So, again, the devil's in the details.

Mike suggested beefing up the chapter language as one alternative. We might even have a third recommendation that says, you know, clear definition of what constitutes a

different service, what constitutes a different outcome, what constitutes evidence. Something like that would be more -- you know, somebody has to -- I don't think we should be the ones, though, that develop guidance on that. We should just identify that those are things that need to be clearly defined to have this thing be successful.

And then with the risk of going back to round one, it just stood out so sharply to me, the proton therapy example where it says if they're just outpatient surveillance, it's $820; if it's IMRT, it's $20,000; and if it's proton therapy, it's $49,000. I'm not sure how that price, for example, got set, but it does kind of highlight this need for definition on all of these. Is it a different service? Does it have a different outcome? And is there evidence of that? I mean, it just kind of strikes you that -- and Ron I'm sure has got all the data on that one to know the answer, right? But that kind of highlights the need, I think, for the definition piece of this as part of the recommendation.

MR. HACKBARTH: Let me just pick up on the points that Peter and Mike have made. I agree with Peter that we're not really the right place to lay out in great detail

the answers to the important questions Mike has raised.

Having said that, I think we need to think enough about the questions that Mike has raised to be confident that we're not recommending something that really is impractical or impossible to do. So I'm sort of between you. I may be a little closer to Peter than to Mike, but I think these are important issues that Mike has identified.

MS. UCCELLO: I agree with a lot of the comments so far. I think it's a really important step in the right direction, moving toward this.

I want to go to Recommendation 2, and this was brought up in round one on putting the onus on the developers and the manufacturers to prove that it's superior. In this week's Health Affairs, there was an article about having a three-tiered system where it's proven that you're superior or that it's comparable, which would be the LCA type of thing, or a third category where there's insufficient evidence, and then you would have three years to prove. I mean, that seems to make sense to me, but I don't have enough information to evaluate what's more appropriate here -- putting all the onus on the developers or having this kind of period for insufficiency of

information.

I guess I just don't -- I would like more information on when something new is developed, how much information is there already to determine whether something is superior or not; and if it's not available by then, how long does it take to get that information? And I think it depends, but --

MR. HACKBARTH: In the Health Affairs piece -- this was Steve Pearson's article.

MS. UCCELLO: Yes

MR. HACKBARTH: That third category where there's no evidence, how is the price set there?

MS. UCCELLO: According to current Medicare pricing.

DR. MARK MILLER: Exactly. In this context, you would be letting it go to the higher price if the manufacturer was driving the higher price.

MS. RAY: And it would have that price for three years [off microphone]. Sorry. So if it didn't have evidence showing it was the same as or better than existing options, its payment would be set based on existing statutory formula. It would have three years to produce

evidence to show, you know, how it would compare.

MR. HACKBARTH: So what I hear you saying is if there is evidence, the manufacturer can set the higher price; if there isn't evidence, they can get the higher price but for a time-limited period. If they're --

MS. RAY: If it has evidence that it's better, then it can charge a higher price. If it has evidence that it's the same, it's a least costly alternative.

MR. HACKBARTH: Right.

MS. RAY: If it has no evidence, it could get its higher price based on the statutory formula for three years.

MR. HACKBARTH: Yes, that's --

MS. RAY: Oh, okay. I'm sorry.

DR. CASTELLANOS: Thank you. I guess I should start my comments on that I've lived with LCA with Part B drugs and it works. It really does work, and it's effective, and it's good for the Medicare system, it's good for pricing, and quite honestly, it's pretty good for patients, too, when the patient has the option of electing to do something different if he or she wants to or if it's medically necessary. So I really think it does work when it's properly applied.

Now, as far as Draft Recommendation 1 and Draft Recommendation 2, I think Peter really hit the nail on the head. I think we can drill down too much and be caught in a cesspool if we're not careful.

I think Nancy brought up two services, new services. Now, Peter briefly brought up that example that you used on page 29 of radiation therapy, and you're comparing observation and radiation therapy. I'm sorry, those aren't similar services. They're just -- they're similar options of treatment, but they're not similar services. And you have to be extremely careful on your definition of services, and Nancy brought that up. But, again, you can't -- those are not similar services. And if you want to do that, then you better start talking about radiation therapy, chemotherapy, surgery, and all that. So I think we're way off by this example, and in my opinion, it's a poor example.

MR. HACKBARTH: You're making Mike's point [off microphone].

DR. CASTELLANOS: Yes, I'm making Mike's point -- I'm making Mike's point.

The last point -- and, you know, Bob is going to

make up my other point because he's going to talk about lack of evidence. I don't like that definition, and I'd like to know who's going to make those decisions and how it's going to be done.

You know, again, some of the things we've talked about over the last several years need to be incorporated in this: comparative effectiveness, appropriateness, guidelines of treatment, et cetera, done by the societies. We need to talk about informed decisionmaking, too.

You know, least cost alternative is a good, good option, but when costs become the primary determinant, then we can really get in trouble.

Thank you.

DR. BERENSON: Okay. Here's what I'm going to say, Ron. No.

[Laughter.]

DR. CASTELLANOS: I've got my tape recorder on.

DR. BERENSON: Yes. I support Draft Recommendation 1 and I support the thrust of Draft Recommendation 2. I think it's much more complex than this -- as this conversation has started to get at. And it may vary by services. I think, for the most part, for Part B

drugs, the FDA process, at least for on-label use, determines what the outcome is. I mean, the two drugs for prostate cancer sort of as part of the FDA labeling, they establish what the purpose is and we don't have a head-to-head comparative effectiveness, but the drugs are used for the same purpose and I think it's relatively more straightforward to get the evidence. For off-label, it's trickier.

I think for DME, I think it's often fairly straightforward to figure out that two different services are achieving the same objective and they can be compared.

When it gets to sort of medical and surgical services, I think it's much trickier, and so Draft Recommendation 1 contemplates that this might be extended.

The work that Peter Neuman has done looking at now 150 consecutive national coverage decisions by CMS found that in the majority of cases, there is either poor or no evidence on which they had to -- or poor or fair, I should say. It was either fair or poor evidence on which they had to make a coverage decision. And if we hold to a standard of you have to have good evidence, I mean, if the burden is such that if you don't have evidence, that it's not

approved, I think you need some kind of outlet like Pearson is suggesting. I don't know whether the three years is right or not, but I think we need -- there are things that come along where there might be a compelling case to approve something while the evidence is being developed and I think we have to somehow consider that.

This is a process where we are going to use pricing to essentially affect coverage as opposed to the more straightforward we are going to give it a coverage up or down. Here, we are going to give it a price, and that price may effectively make it not covered, if you simply -- so I think we need some kind of an exceptions process for the Secretary where there is no evidence or we have a process like Pearson is suggesting.

But that brings me to the final point I wanted to make, is that there is an assumption that these services are a manufacturer or a pharmaceutical company who have the potential of gathering monopoly pricing and they will have an incentive to then fund the studies to get the evidence. Services for which nobody can achieve monopoly pricing, there might not be sort of that natural funder of the studies. A surgical procedure that doesn't include a

device, who is going to fund that? That is, I assume, comparative effectiveness will pick it up, but again, you may have a bias towards drugs and devices and not to other services for which the evidence simply isn't being produced if -- and so I think that -- all I'm saying is I think there's some complexity here that simply saying the absence of evidence means you may not get into the system, I think we need to think through those situations a little more carefully.

I don't think I need to get into the Lucentis-Avastin thing that I was going to.

DR. MARK MILLER: The only thing I would say, your last comment that you don't get into the system, you would get in, just at the lower price.

DR. BERENSON: Yes, but for some -- I mean, if you truly have a different service that you simply can't produce at the lower price, you are effectively not in the system, and so -- actually, I will use the Lucentis-Avastin thing because it has been brought up by a couple of you. They are two alternative treatments for acute macular degeneration. The on-label drug Lucentis is the one that costs $2,000 an injection. The off-label Avastin is the one that costs $40

or $50 or something.

Interestingly, the Academy of Ophthalmology actually endorsed the off-label use without the clinical trial that we're anticipating, the head-to-head clinical trial. It seems to me that's a situation where you probably want to invoke least costly alternative where you don't actually have the full evidence that has come in, if your advisory committee or whoever you're going to have here can agree that there's no sort of compelling need to wait for that clinical trial to be developed.

I'm just saying there will be some situations in which the potential benefit of that service is such that you really need to make a decision today with some window to get the evidence, tighter, I think, than what we've got with coverage with evidence production, which I think there's some looseness to. But that simply saying we're not going to price anything other than to the least-costly alternative in all cases without evidence, I think, is too strict a standard, and so I think we have to work through some kind of an exceptions or some time period or something like that, which I don't think we've worked through yet, something like what Pearson is suggesting, or I'm not sure exactly what it

would be.

MR. KUHN: I'm kind of going back to where Glenn was sharing his thoughts on this kind of three areas that you're looking at, is that if you really think about the Medicare today, the Medicare program truly is, except for the MA side of it, but truly is a passive payer of services. It just simply pays the bills when people get sick and that's pretty much what it does and it's pretty darn good at paying those bills.

I think what we're hoping to do here with this discussion and others is really help the Medicare program become more than a passive payer, but become an active purchaser of high-quality efficient care. That's where the Medicare program needs to be in the future and where I think its salvation rests as we go forward.

So again, I think this policy and both recommendations move us in that direction and I think they're both solid recommendations and have a lot of merit.

Of the two, however, I think that the second one -- let me share a couple of comments about that one. On the second issue, you know, the real issue here for me is that, as you heard in terms of the report that laid out the IR

process, Inherent Reasonable process, just is not an effective process. It's not being used. It's hard to implement. So some way to kind of circumvent that, which Option 2 allows you to do.

Also, to me, Option 2 reminds me a little bit of coverage of evidence development. Yes, we're going to cover it, but you prove the evidence that there's higher value here and we'll more in that direction and we'll support you in that.

And so what I can see coming out of that is that folks may recall when Sean Tunnis was here not long ago and we were talking -- one of the issues we were talking with Sean about is the parallel review with the FDA. And remember, the authority of the FDA. Theirs is safe and effective. Under the Medicare, as we have talked about, under this 1862 provision, it's reasonable and necessary. And so I think one of the innovations that you would hope with an option like this or a recommendation like this is you would see innovators thinking about the value of their product long before they are through the FDA process so that when they show up at Medicare's doorstep, not only do they have a stamp of approval from FDA in terms of safe and

effective, but also they're ready to address the reasonable and necessary issue head on. And I think it just front-loads a lot of that investigation, a lot of that work earlier, which I think is value to the program and ultimately value to the beneficiaries that are out there.

I think all the issues we've talked about here in terms of making sure it's a very transparent process, it's a very rigorous process, it's one that's based in evidence, is going to be absolutely key, I think, for the Medicare program to maintain its credibility. But again, I think both have a lot of merit. But I think they also will help spur innovation even further.

But importantly, like I said at the beginning, is that what we really need to do is help Medicare become an active purchaser of care and I think this -- both of these options help us move in that direction in a pretty effective way.

DR. KANE: Yes. This discussion reminds me of an article I wrote about 20-odd years ago that Glenn reviewed, and he didn't like it the first couple of rounds, but it finally got published.

[Laughter.]

DR. KANE: What it talked about was the process by which new technology got into the DRG system and the fact that manufacturers would fight to get an ICD-9 code attached to their new device that was at a higher -- it was actually the cochlear implant at the time, but it's a known method of profit maximization to try to get your device or procedure or service into a better ICD-9 code or a new ICD-9 code that would put you into a new DRG.

And in a way, that's the prospective payment system's way of doing the least cost. You're getting it into a clump of comparable services and there's going to be a range of what it really costs to do it the different ways, but you're going to get the average price.

And this starts to bring -- and the reason I asked where we really want to apply this is I really think we already have some of that kind of, you're in a cluster of services already with PPS, with prospective payment, just by virtue of the way that you've got to get a code and these codes cluster services together. But we don't have it for drugs and devices. So in that sense, I think we're not being -- all these decisions are being made already for a lot of all the services, just by virtue of a process that is

not very transparent, which is what my article was about. It's the coding process. How do you get an ICD-9 code.

So I'm not that uncomfortable with the idea that we apply this also to drugs and devices. And my only concern really is that I think we're being a little naive about the industry response. So the example you gave me about how industry behaved when LCA got lifted was an opportunistic example. So they kept their prices low and then they jacked them up when the constraint went away. But I'm thinking back to when, for instance, generics started to become a threat to brand names, and what was the drug industry's reaction to that, was to try to repress the bringing to market of generics. And I think -- and I actually think I mentioned this before -- I read a thesis of a doctoral student who studied the introduction of lower-cost alternatives to your existing brand and in markets where there are reference prices, they didn't bring it in, and in markets where there wasn't, they did bring it in.

So I think we do want to have maybe some way, and I'm still all for LCA, but I'm thinking there should be some way you can see what is being introduced on an international basis so you know whether or not this is happening. We've

traditionally buried our heads in the sand and said, well, only the U.S. counts, but the drug market and the device market are global markets and why shouldn't we expand the world that we look at outside our borders, especially if you start doing LCA, to be sure that we are not only getting the brand name and not the generic that they're introducing someplace else because there's no reference price, or least cost.

So I support the recommendations. I think we shouldn't make it such a big change in policy because it varies somewhat with what goes on with prospective payment now, but I think we should be cautious about how manufacturers will, when the rules overall are changed, how they might change their product introduction strategies to not introduce products that might be lower cost because they don't want to have everything in that cluster go down to the lower price the way generics did and were repressed for years.

So that's probably enough.

MR. ARMSTRONG: Just very briefly, I would also like to affirm that I support these recommendations, particularly given the comments made about definitions and

so forth. But I wanted to just take a few seconds here to also acknowledge, I think, Glenn, I thought the way that you framed the context for this as this group striking a balance between how we advance innovation versus control costs, and Herb, your comment, too, about our role more as an active purchaser is just a point of view about -- and your point in particular, that we need to lean more toward managing our costs, is a point of view that I completely agree with and I just wanted to take a moment to say that.

MR. GEORGE MILLER: Very briefly, I also endorse the draft recommendations and particularly want to highlight the comments Nancy made concerning reference pricing and dealing with that whole issue. I think she's right on point with that issue. And because this is a global market of both drugs and devices, we should look outside the United States to try to find the right perspective.

And then to my question I raised earlier, since the recommendation talks about an expected decrease in spending, I reflected on comments that Herb made in previous meetings. We should make sure that the Secretary and thus CMS has the appropriate administrative staff to implement this because the potential savings are very, very large.

And so if we get this recommendation passed but the agency doesn't have the infrastructure to make this work because of staffing issues, then we may not get the savings because they have got so many juggling issues, and I think Herb brought that issue up before, appropriate administrative costs to handle this.

DR. BAICKER: Just to put a slightly different spin on this issue that Nancy and George have raised, I think the move towards reference pricing seems like a great one, and I think this largely reflects my own ignorance on the issue, but it makes me wonder whether it's an opportunity to revisit how those reference prices are set in the first place, that the system is only as good as the mechanism through which we're setting the price of the least-costly alternative, and it's not clear from what has been said that that doesn't bear some scrutiny and potential improvement, and that might fit in well with a move towards bolstering the use of LCA.

DR. DEAN: Yes. I, too, certainly support the general thrust of these recommendations. Obviously, there may be some tricky issues as far as the actual wording.

I think we need to take a step back. I think it's

truly unfortunate that the legislative language about the comparative effectiveness sort of prohibited that data from being used in this kind of a context, because if you are not going -- I mean, the whole point of comparative effectiveness is to understand the value of an intervention, the value of a service, the value of a drug, and how it relates to what we already have. And if that doesn't have an impact on pricing, then where's the market? I mean, it's fundamentally essential if we're going to have a market response.

And so I think that -- I'm not sure what the next step with regard to that is, but comparative effectiveness research is clearly essential for us to make both clinical decisions and market decisions. So I would hope that we can be on record to support that approach. I don't know exactly what the next step would be.

As far as in those situations, I would support a lot of what Herb just said. If we have situations where data does not exist and there is an item that looks like it has promises, we do have a fallback position, which is the coverage with evidence development. It would seem to me it would be in a supplier's best interest to agree to that and

even to support it if they have a product that is promising and yet they can't document that or they can't prove it. Setting up registries and those sorts of things are not terribly onerous kinds of things. It may well be, because of the problems that we have already talked about, that CMS does not have the resources to do it nor should it necessarily be their responsibility. I think it is the responsibility of the supplier to prove the value of their product, and that's a relatively easy way to do it, I would think.

And then just finally, a comment on the off-label versus on-label issue, which we would all probably feel better if something has been gone through the process, and yet I refer back to the colchicine experience that I just talked about. In that case, the value of the product probably decreased and its applicability and usefulness decreased after it went through the process, because now it's been priced out of the reach of a lot of people, and it's a drug that's far from perfect, but it has some very useful applications.

And so I'm not sure. I mean, it really creates a bit of a dilemma. We had a good drug. It wasn't a perfect

drug. It had lots of side effects. And yet it definitely had a place. And now it's so expensive that unless there's some sort of third-party coverage, we don't use it. So anyway, whatever that's worth.

DR. STUART: I'll go on record as supporting the two recommendations. In essence, I agree with the conversations around the table that there are clearly exceptions that we're going to need to do and we're going to have to spend time looking at the specific language.

I want to raise something that we have talked about in the past, we haven't really addressed it much today, and that's heterogeneous outcomes. If you've got a product that has -- is homogeneous in its outcome across patients, then it's relatively easy to go through this process and it's also relatively easy, or easier, to get the evidence.

It's much harder when a company can come and say, well, it may not work in patient A, but it's going to work in patient B, and then that extends through the rest of the alphabet. For that reason, trying to figure out what the evidence is for all 26 of these circumstances becomes pretty daunting. And so part of that -- and I know that's going to

come up. I mean, that's a loophole through which trains can go through. So that's something that I think we want to pay attention to.

And I think for that reason, the language that you have in the chapter is important, because one of the bullet points is that it says this process should ensure exceptions and individual considerations to the least-costly alternative policy when a beneficiary's clinical circumstances support the medical necessity for the most expensive service. Now, that sounds like there's evidence that says it works for patient B even though it may not work for patient A, but I'm not sure that that's what you meant by it. And then down below that, it says, permitting a beneficiary to gain access to a more costly product, if that is his or her preference.

Now, I think the weasel in the words here is access, and do you have in mind here that the process, the least-costly alternative would be the base price and if somebody wanted to pay more for a more costly service, then they would have that option, which I think we could all probably agree with, or does it mean, that first bullet point, that the program would pay the higher cost if, well,

whatever. I am not sure what the circumstances would be. But I can see that being a very important consideration when you actually get down to the ground in developing the regulations.

MS. RAY: I think we are suggesting two processes, one in which the clinician makes a judgment that the more expensive item, there is a clinical justification, and that there could be a process set up that somebody could review that, like the contractor medical director, and look at the patient's history and look at the -- and do a literature review, and based on that make a decision.

Then there's a separate --

DR. MARK MILLER: In that instance, the program would pay for it.

MS. RAY: Right.

DR. MARK MILLER: It would get the higher-cost drug. In the second instance, it's a matter of choice, where the beneficiary says, even though there's no clinical indication here, I want to pay the difference and get the higher -- so it was an attempt, whether it was clear or not, to lay out two separate exceptions there.

DR. STUART: [Off microphone.] Well, in the

private market, one of the approaches to this is the fail first. In other words, you're on a drug. If there's no progress shown, then it doesn't -- there is not a strong evidence base that has to be met. Rather, it is the lack of response to the first product and that generates access to the second.

DR. BORMAN: In the main, I'm supportive of the recommendations. I think the Recommendation Number 1 is closer to a final version than perhaps is Recommendation Number 2.

Just to sort of start from the beginning, I think relative to the chapter, I think it would be helpful to have sort of a bit of a broader context introduction, Glenn, whether it's some of the points you outlined, how we see this, as Herb framed it, from going to the passive payer to the prudent purchaser, perhaps, a bit of that conversation, just some of the things that lead us all to have the sense that this is a direction we want to go, I think, rather than this coming across solely as a technical exercise, because I do think it's more than that. I think it represents -- it is a technical exercise that's going down a road that we believe we want to go, and I think it's important to start

out with that information as a context center for it, so I would advocate for that as the materials evolve.

I think that, if I heard Peter correctly, he's suggesting maybe that there has to be another recommendation that gives some specifics about processes or criteria or something like that, and I'm a little bit torn whether that should be a recommendation or whether that just needs to be fairly detailed supporting language, and I think as this evolves, perhaps staff is going to need to help -- is really going to have to use good judgment, as they always do, to help us know what goes in what piece of this and how we best convey it.

I think that it would be presumptuous of us to attempt to define clinically similar. I just think that is stepping way outside our boundaries, just as it would be way outside our boundaries to say the Congress in the next session should do X. I just think it takes us down a road we don't want to go.

On the other hand, I think those of you that do or have touched patients periodically in your lives have a pretty good sense of some of the criteria you would use to define what are clinically similar. You can certainly take

this to all kinds of definitions in a thesaurus and whatever else, and I think the concern -- and I think as I mentioned last time, I think for equipment and for drugs, it kind of is a natural. I think as we start to move outside that, there are potential problems, but my personal first blush would be that when we go to compare things that are seemingly less alike, that is a drug versus an operation for something, I don't think this is going to come into play because I think you are going to be talking about a package of services versus a package of services, and not that there's going to be a head-to-head this and this to compare. And so I think in practicality, that part won't play out so much.

I do think there are some places in the testing world, whether it's imaging or lab, where it will come into play and it may cross those two, and just off the top of my head would be tests for detection of H. pylori infection. There are things that relate to nuclear medicine, to isotopes and things that relate to serology and some different things that might start to cross some of the boundaries. But by and large, when you start crossing BETOS boundaries, probably you're going to start talking about

contrasting bundles and I think that will be less of an issue than maybe we think it is on first blush.

And then I think that some comment about the Secretary needs tools and resources to make this happen, a fairly explicit comment about that, whether that comes in the form of a recommendation or in supplementary material, I think would be very important to all of us. We don't want -- this is important enough to do. We don't want to do it half-assed.

And then my own final item would be, I think, some comment about PCORI and other sources, maybe that we say these might be some potential sources to bring to bear on this process and help us to -- I think we all found value in what Mark said about where we hope PCORI will fit into this. Let's be proactive about maybe helping to push where it will fit into it through our comments about it. So those would be my thoughts.

DR. CHERNEW: I just want to say in response to Karen's comment, I think we run the risk if we don't say something more about clinically similar, of each of us thinking that it is, but we think it is because obviously what we think has to be, and then it turns out to be someone

else's view and then we're not so happy about it.

So I think it actually does behoove us to be a little more explicit, as Ron's point about the prostate cancer stuff. He was, like -- at first, he was -- I might be misinterpreting you, Ron. His first view was, well, we don't really want to get into this all that much, but this particular example, that's just completely wrong. They're not similar. And I think in Karen's point, the same way. You think, we won't cross BETOS categories. But I think a lot of people will think that they will cross BETOS categories. And if we mean not to cross them or to cross them, we should say and have that discussion, because clinically similar may have, if you read the examples, same mechanism of acting, same outcomes, similar, you know, there's a lot of different things in the examples of what that means. I don't think we need to go into exact detail, but I think three or four principles about what we mean by that would make this a better, as opposed to a worse, chapter.

DR. MARK MILLER: [Off microphone.] -- point just from a practical execution point. The way I was going to try and navigate the two different views on that and some of

the comments that were made here is if we can't go out, and I think you're correct, we can't go out and define it in any way that this group could come to in any timely way and that anybody would end up being perfectly happy or the rest of it, is to try and walk through different ways it has been defined in the literature, in trials, in places like that, and say these are some of the ways clinical similarity can be viewed. That would be one way to kind of execute this and say, here are some ways it's been approached in the past, as opposed to picking them.

Your other comment was, well, could we at least define principles, and I would have to do the first exercise to even know whether I could get to the second.

So that was the way I was going to try and navigate that and probably not try and build it into the recommendation, but say we have used this term in the text. These are the kinds of things we are talking about, and then try and draw from the literature on what those things are. Now, if that happened to point the needle on the compass, oh, so these principles are really clear, great. I'm just not convinced in my sense that it would be really crystal clear.

Just a couple of other things. I mean, in terms of take-away here, I'm generally hearing consensus on the first recommendation and some question about the wording, and most specifically the clinical similarity.

More reservations on Recommendation 2, not outright opposition, but reservations there. And some of the things expressed that maybe there needs to be exceptions, time periods, rolls into CED if we don't stay with this kind of head-on, and definitely there were some definitional issues in here that would probably have to be talked about, again, perhaps using the same strategy. Here's some of the idea of what we mean by this.

I definitely heard a couple of strong statements about -- and if we're going to talk about moving forward with this, let's not forget that there are people who have to implement it and that they have the tools and the resources to do it. I heard that.

And then I heard some, and this is kind of an interesting point. I think -- I'm just going to say this because I wasn't quite sure how it came out -- definitely a sense that if you're going to do this going forward, you may have to think about services that are not the same, you

know, a medical versus a surgical or a medical versus a drug, but definitely a statement that evidence readily coming out in the short-term on head-to-head things like that are going to be much less likely to be around, although I do understand what your comment is. Going forward, maybe not so much. I did hear that.

But I definitely felt that I heard a little bit of that, and so here's really what I'm fishing for, is I still get the sense that people felt that if you go forward with this, you've got to think about it broadly, because otherwise the substitute for something that you're setting the price on could be completely missed in the process and you could fuel some behavioral change. So the drug for this thing, the price got set low, so I'm moving over to radiation therapy and then that takes off. I got the sense that some people were concerned about that, but with a recognition that head-to-head evidence on that is going to be a lot more complicated.

So that was my take-away from this session, and since we've got to go back and begin to kind of tool up and bring it back, I wanted to make sure that I had a sense of what happened here.

MR. HACKBARTH: Good.

MR. BUTLER: One final note, because I was the one who recommended having a Recommendation 3 as only to -- if you tell us yourself, these things are taken out of context, and if they're just the freestanding specific recommendation and we don't somehow acknowledge the definitions are important, then we've missed the point. I realize the definition points that are being made can't be fully made in a recommendation by itself. They have to be articulated, as you pointed out, in the text, in addition to. But I just didn't want the concept of definitions to be, you know, absent totally from the recommendation statements.

DR. MARK MILLER: And I think that you framed that very well, because it is our experience that people take our recommendations and selectively -- the supporting material can be selectively reported, and so you made your point.

DR. BORMAN: Glenn, just one thing, also, that I thought most of us would agree to would be that if we do start looking at some sort of exception or other process for new things, because we all recognize the balance here between, Glenn, as you have pointed out, innovation and cost, that if we elect to support kind of an alternative or

a time frame or whatever it is, that it clearly be tied to some sort of data collection registry, something, whether it is expanding it through the CED process or something. But there needs to be a way to track it so that it's not a carte blanche for forever to just bring in technology at a higher price. I think just that point of making sure that there's a tracking mechanism would be a very important one to make.

And then in the beginning sort of introduction, we might also mention some of the benefits that technology has brought to our delivery care system so that we make sure we say we're looking at the technology innovation cost balance.

DR. BERENSON: Briefly, I agree with Karen that we need to sort of close the loop on this. I still have a concern which nobody really sort of joined, that there's an assumption that there's an owner, the manufacturer, the pharmaceutical company, of producing the evidence, and that there are some services for which there is no owner. And we have to think through, how do we get the evidence in those kinds of situations so those kinds of services are not uniquely disadvantaged.

MR. HACKBARTH: Okay. Thank you, Nancy and Joan, for your assistance.

Next up is validating the physician fee schedule's time estimates. Kevin, whenever you're ready.

DR. HAYES: Okay. Thank you. Good afternoon. I'm here to talk about validating the fee schedule's time estimates. This topic relates to provisions in the Patient Protection and Affordable Care Act concerning misvalued physician services.

CMS has requested comments on approaches and methods the agency should consider in fulfilling the act's requirements. The intent of this session is to begin your consideration of options for CMS, including options for validating the fee schedule's time estimates. Separately, we have work underway to address these issues and will have more to discuss at a future meeting.

The first of two provisions in PPACA directs the Secretary to review the RVUs in the physician fee schedule and to apply criteria to identify services that may be misvalued. These would be criteria along the lines of services that are growing rapidly, services that involve use of new technology, and that sort of thing.

The other part of this provision in the act directs the Secretary to make appropriate adjustments in

RVUs if the services are found to be misvalued.

In the proposed rule published this past July, CMS said that it has been working on these issues for some time now, working with the American Medical Association Specialty Society Relative Value Scale Update Committee, or RUC, and that the agency has identified and reviewed numerous services according to the criteria of the sort identified in PPACA.

So that is the first provision. It focuses on applying criteria or decision rules, if you will, identifying misvalued services and making appropriate adjustments in their RVUs.

There is a second provision in the PPACA, however. It directs the Secretary to assess the validity of the fee schedule's RVUs. CMS' interpretation of this provision appears to be one of this requiring use of some sort of external data to assess the validity of fee schedule RVUs. And I say use of external data because of something that CMS said in that proposed rule about how they were especially interested in approaches to fulfilling this requirement that involved use of time and motion studies. And so that would be an example of a kind of thing that would involve some use

of external data. And it is this second provision in PPACA that I would like to talk about today.

Aside from expressing interest in time and motion studies, CMS did not offer a specific proposal on how to validate the fee schedule's RVUs. Instead, the agency has requested public comments on possible approaches and methodologies that could be considered.

To begin consideration of this issue, we need to revisit some points about how services are valued in the fee schedule.

In passing legislation in 1989, the Congress intended to remedy some of the problems inherent in the previous charge-based payment system. For example, that system was viewed as inflationary.

The fee schedule was a departure from payments based on charges. It was a system that included development of relative value units that addressed the relative costliness of different types of inputs used in furnishing physician services. Inputs are listed here. These would be the work of the practitioner. This would be practice expenses, the cost of renting office space, of employing staff, of buying supplies, equipment, and so on. And then

the third input identified in the law was professional liability insurance.

In considering the different types of inputs required, it is clear that physician services are labor-intensive. The work of physicians and other practitioners -- - such as nurse practitioners, physician assistants, and psychologists -- accounts for 48 percent of payments under the fee schedule. Compensation of employees working in practitioner offices accounts for another 19 percent. If mispricing of services in fee schedule is to be corrected, the effort is likely to require consideration of the way the fee schedule accounts for labor costs and, as we shall see, the fee schedule's estimates of the time that practitioners and their employees spend in furnishing services to patients.

For the sake of clarity, I will focus in this presentation on the work of practitioners as the input and how it is valued in the fee schedule, but many of the concepts I will discuss about validating RVUs apply also to the labor inputs that are identified as practice expense.

So how is the work of practitioners valued? According to the Medicare statute, the fee schedule's

payments for work can account for two factors: time and intensity. Time is just that: It is the number of minutes required to furnish a specific service. And then I will come back to that concept in just a moment.

By contrast, intensity is the more subjective of the two concepts. Intensity includes things like effort, skill, stress, mental effort, and judgment.

It is useful to think of the work RVU for a service as a summary measure or composite of these two concepts, time and intensity. To establish a service's work RVU, physicians and other practitioners are surveyed and asked questions about the service's intensity and time using a method called magnitude estimation. Note that the method does not include use of a formula that weights each dimension of work to arrive at a composite score, or the RVU. Instead, physicians are asked questions about a service's time and intensity and asked to integrate these dimensions in whatever proportions are relevant to them. They are then asked to compare the time and intensity of the subject service to other services for which RVUs have already been identified. Then as a final step, they are asked to estimate an RVU for the subject service.

When this process of magnitude estimation is complete, there is a set of time estimates available -- estimates that were used in the valuation process. For example, the time estimate for the most frequently billed office visit is 23 minutes. Time estimates for diagnostic services tend to be a bit shorter, a bit lower. The time estimate for a chest X-ray, for example, is five minutes. On the other hand, procedures tend to have higher time estimates. The estimate for a knee replacement is almost two hours, not counting the pre-op and post-op visits involved.

The process does not, however, produce a set of numbers or estimates for intensity by itself. We can only infer intensity with statistical methods.

Doing such an analysis, we find that time has a lot to do with how the work RVUs are set. The fee schedule's time estimates explain between 72 percent and 90 percent of variation in the fee schedule's RVUs, depending upon the type of service. In other words, what this is saying is that within these categories, intensity on average does not have a lot to do with how the RVUs vary for different services. Instead, it's the time estimates that

seem to be the most important determinant. If the goal is to ensure the accuracy of the fee schedule's RVUs, it seems fair to say that it is necessary to ensure the accuracy of the time estimates.

Questions have been raised about the accuracy of these estimates. Contract research for CMS and for the HHS Assistant Secretary for Planning and Evaluation has shown that the time estimates for evaluation and management services and major surgical procedures are likely too high. But what about the estimates for other services such as imaging, tests, and procedures, procedures that are not major procedures, procedures such as colonoscopy or maybe removal of a skin lesion?

Other questions concern the circumstances in which a service is furnished and whether, during a single patient encounter, a physician furnishes more than one service for the patient. According to a study by GAO, the fee schedule does not adequately account for efficiencies occurring when a physician furnishes multiple services for the same patient on the same day. This raises the question of whether the time estimates are adequately sensitive to such efficiencies?

Let's pause here, if we can, and just think about where things stand. We have the matter of the PPACA and its requirement that CMS validate the RVUs. We have the time estimates, which appear to be an important factor in valuing services. We have questions about whether the time estimates are accurate.

And so it looks like some kind of data collection activity might be required here to fulfill the PPACA requirement, to validate RVUs, and to assess the accuracy of the time estimates. CMS has asked about time and motion studies as a way to go about doing this. As we will see in a moment, perhaps there are other approaches.

And it's also worth noting here that this is not the first time that issues of data from physicians services have come up. CMS has not discussed a strategy for updating the data used on practice expense for practice costs and how they vary among physician specialties. Without a recurring source of practice expense data for all specialties, practice expense payments may become inaccurate over time.

So on this issue of data, you know, the Commission, of course, has been here before. In the June 2006 report, the Commission discussed the accuracy of data

that CMS uses to value physician services. The context then was practice expense, but at the time there were certain principles articulated that would apply in the current set of circumstances about validating fee schedule RVUs more generally. For instance, all types of practitioners furnishing services to Medicare beneficiaries should participate. If that does not occur, there is a potential for changes in payment rates that might distort payments one physician specialty, let's say, relative to another.

In the 2006 report, the Commission also discussed the importance of having processes in place to ensure data accuracy. Then there was the matter of CMS and having adequate resources to take on new responsibilities in this area. So that is a set of principles that might guide us in this topic.

The June report also talked about different ways to go about collecting data relevant to validating RVUs. One approach is to conduct voluntary surveys, and there has been some experience with this. Most recently, we have the American Medical Association, physician specialty societies, and other professional organizations collaborating on a physician practice information survey. There has also been

experience on the part of CMS itself in just trying to go about collecting data with surveys. The difficulty here is with response rates. It is not unusual to go through a survey exercise and end up with a response rate of 10 percent or less. And so, recalling what we talked about a moment ago having to do with representativeness of data, when you're talking about very low response rates, there's a question about representativeness.

So to try to get away from this vexing problem of low response rates, one alternative might be to go about a data collection effort at physician practices and other facilities where practitioners work. This would be facilities such as multispecialty clinics, multispecialty group practices, and so forth, and go out and try to collect the data that are needed.

The way one could go about structuring this, we see some ideas listed here, but it would be a case where practitioners would be identified, asked to participate, and they would have to participate if asked. Of course, there could be provision for some compensation for doing so.

The effort would also require a change in regulation. It would require some buy-in on the part of the

physician community. But what this would do is it would open up some options for how data might be collected, and so I wanted to talk for a few more minutes about how this approach to things might work.

Participating practices would provide data on time, on the volume of services, and other factors that are important in valuing services. They would be recruited through a process that would require participation, but that would ensure that the data collected would be representative of all the practitioners furnishing services to Medicare beneficiaries.

The cohort of practices involved would be large enough, would need to be large enough for estimates that meet criteria for statistical precision. The practices could be compensated to account for the administrative costs of participating in the effort.

Of course, such data collection would present implementation issues both for CMS and for the practitioners involved. For example, if we talk about issues for CMS, there would be questions about what data sources to try to draw from for this effort. Some data sources could be what you might think of as retrospective in nature, so this would

be data that are already available through systems such as maybe patient scheduling systems or electronic health records.

The other option would be some sort of more prospective-oriented data collection where new data would need to be collected, and that example earlier of time and motion studies would be a way to go about collecting data prospectively.

Another set of issues has to do with just the number of participants that would be required, and the numbers here, of course, would need to be sufficient to ensure the reliability of the data collected. An issue would also be of compensation of practices, and if so, at what rate.

Then there would be some issues having to do with the unit of measurement. One could imagine trying to collect data at the level of each discrete billable service. Another way to do this would be to go at a more aggregate level and to try and collect data, say, at the level of the practitioner, number of hours worked over the course of a week, month, year, amount of time spent on patient care activities, and the mix of services furnished.

Other issues for CMS have to do with the method of data submission and ensuring the accuracy of the data submitted. Who would collect the data? Would practices submit data according to a standard format or would some kind of field work be required on the part of a CMS contractor? If practices submit the data, would CMS need some kind of audit capability to ensure data accuracy?

We have other issues listed here having to do with whether the cohort of practices would be consistent over time or whether we would have practices rotating in and out of this cohort. And then there would be issues perhaps having to do with -- in the case of time measures and others, having to do with whether these measures vary by geography, by service mix of the practice, and by the practice's payer mix.

Issues for the practitioners would also involve the method of data collection, what types of data would CMS try to draw from. Would it be electronic health records? Would it be patient scheduling systems? What, in fact, would -- where would the data be coming from and what are the implications of that for their practices and how they operate?

Another issue has to do with just what this data could mean for the practices. Are they using such data for their management, for practitioner compensation? That might affect both the utility of the data from the standpoint of practices but also of what they already might have available.

Then there's the matter of just having comparative data and whether practitioners would see some value in how their practice compares to that of their peers.

So to conclude, the purpose of this session was to make sure that you are aware of the PPACA requirements on misvalued physician services; to point out that CMS has requested advice on validating the fee schedule's RVUs; and to also seek your comments on an approach to collecting data that would be needed to validate RVUs and keep not just work RVUs but also practice expense RVUs up to date, and then some of the implementation issues that would accompany all that.

Thank you.

MR. HACKBARTH: Thank you, Kevin.

Round one clarifying questions?

DR. BORMAN: Kevin, this is a tough thing to parse

through, and I think you've done a great service in how you started us down the road.

I have a question for you. If at some point in this conversation we could sort of see the element, maybe a listing of the places where all the time factors in, because, again, it's my recollection -- although I'm happy to be corrected -- that physician time goes into both the work and the practice expense calculation. So we really need to know all the places it plays out, I think, and to sort of consciously acknowledge that.

I think a second piece of it is that just as a person who has filled out RUC surveys more times than I care to count, what you do is you do make a conscious estimate of time. At the end of the survey, you make a conscious estimate of the total work. The intensity is largely imputed. There's not a place that asks the survey respondent to say the intensity is 2.5 or 0.67 or whatever it may be. It's a calculation from the time and the work estimate. And while that may seem like a very subtle and arcane thing, I would just want to point that out, because we don't have a valid way of measuring intensity, I mean, other than facetiously putting a heart rate monitor on every

physician and, you know, kind of doing some sort of heart rate variability estimate as the intensity of the service. So just to be crisp, we're doing that.

I would like at some point, whether now is good or not, there's a thing out there that's a scaling factor in practice expense that has set a different value seemingly for similar things that's specialty driven, and it was off the old SMS data. And I'm unclear whether that has gone away because of the PPIS data or not. And if you could at some point either let us or me know sort of where that fits in, because it was another yet relative scale among specialties that seemed to have some profound things here.

I think everything else is non-clarifying.

MR. HACKBARTH: So let me ask a clarifying question of Karen's clarifying question. I'm trying to imagine how these surveys work that Karen referred to, and so broadly speaking, physicians are asked to compare different services to one another, correct? And so they're asked to provide specific information on time and then do an overall comparison, and the intensity is sort of the residual. Am I understanding that correctly?

DR. HAYES: There is one other wrinkle I would put

to this, which is that in addition to identifying, estimating how much time it takes to do the service, physicians are asked questions about intensity and about rating that service's intensity on numerical scales. And it's only after they've kind of thought about the time and the intensity of the subject service, they then turn to the reference services and say, Now, how does this service compare to the references? Is that a fair assessment, Karen?

DR. BORMAN: Yeah. I think the very key thing is what you're given is you rate a service total work compared to a reference list of services. Okay, that's number one. It's a comparative thing, as, Glenn, you outlined.

The second thing is that you are explicitly asked to rate time, and you are explicitly asked to give a total work number. You are asked, as you pointed out, to assign comparative numbers -- I think it's 1 through 5 scale -- for the two things you've chosen to compare to versus the service you're rating. So you might give something a 3, whereas the thing you compared it to is a 2 or a 1 for each of those elements, risk to you, mental effort, technical skill, all those things. But nowhere does it say give me a

number for intensity, and that was my only point, is that it estimates -- intensity is an indirect thing from this.

DR. DEAN: I would sort of echo what Karen said, and thank you, it's a very complex process, and I guess just in the interest of full disclosure, I have serious skepticism about the whole process. But I wonder --

MR. HACKBARTH: We haven't figured that out yet, Tom.

[Laughter.]

DR. DEAN: Is there any element of the process that would account for the huge variability there is from practitioner to practitioner in terms of how they approach any given challenge other than just sort of the averaging out?

DR. HAYES: Yeah, physicians are asked to think about the typical patient when they go through this process, but typical to one physician might be atypical to another one. So it’s going to be a process, like so many other things of this sort, where there’s just going to be variability in responses.

MR. GEORGE MILLER: Following up on that train of thought, in the chapter you talk about implementation issues

and you talked about the design collection targeted at specific types of physician practices. So the question -- I mean, the statement you said was to focus on practices that are efficient as opposed to those that are average.

My question is, compared to what? How do you define what efficient practice is? For example, at least in my mind, if you have an urban physician that has EMR and all the bells and whistles, compared to an older, bearded crotchety physician in some place up north like Montana --

DR. DEAN: You've kind of mixed up your geography.

MR. GEORGE MILLER: Dakota, Dakota, Dakota.

[Laughter.]

MR. GEORGE MILLER: But he may be more efficient, but, I mean -- you understand my question. How do you define what's efficient, who is skeptical, too, by the way?

DR. HAYES: Sure, sure, sure. The point in raising that in the paper was to just point out that this kind of a process lends itself to making that kind of a distinction. We're too early in the process, I think, to say how one would make that distinction, but at least you've got the ability, with a mechanism like this, with an approach like this to say, Well, yes, there are practices

and there are practices, and maybe we want to be a little judgmental about or selective, selective about how we do this. We're not.

MR. GEORGE MILLER: That would be the key issue, the selectivity of the judgment and who said it. Okay.

MR. ARMSTRONG: I think I want to follow up on that question. Actually, the first thing I would say, in my career in health care, I'm glad to say that this is the first time I ever had to really try to figure this out. It does seem kind of archaic. So my question is, I think related to this, we know there's huge practice variation from one geography to another, high cost/low cost areas, urban/rural markets.

Did what you just describe actually deal with building a cohort and collecting data that would accommodate that kind of variation in this process?

DR. HAYES: That was the intention. I mean, if we think about this in terms of design of a research project, that would be the design elements -- that those would be the design elements that would go into the process.

DR. KANE: You're lucky it's your first time. This is a recurring bad dream for me because I've been doing

some of this since the early ‘90s. A couple things. Could you remind me of how many services we need to cost out, I mean, that you’re talking about? Is it something like --

DR. BERENSON: It’s around 7,000.

DR. HAYES: Yes.

DR. KANE: 7,000 services? That’s what I thought. I knew it was thousands; I just couldn’t remember whether it was 7 or 10. It’s an enormous number of services. So part of the challenge is, like that kind of throws time and motion studies, I think, out the window, but you might be able to find what Bill did, which is these reference services that really are the large clusters.

But the other question has to do with, in looking for the right practice, would you want to select across methods of compensation? Like if they are under salary versus fee-for-service versus productivity-based salaries? Because I’m pretty sure they do behave differently depending on how they’re paid.

DR. HAYES: Yes, I would put this in the same category as George’s question, of having the option of doing things like that and that in considering issues of what’s efficient, what’s not, methods of compensation, those seem

like related issues to me.

DR. KANE: But I guess when you get down to it, is the goal to pick the average across all those types or to pay people differently depending on how they're paid? I mean, I'm just trying to figure out what do you do with all that.

MR. HACKBARTH: Or to pay at a level that is compatible with the efficient provider.

DR. KANE: I mean, the other variability would be if whether they, for instance, use a nurse practitioner to do some of the patient work or they use physician's -- I mean, I'm just -- 7,000 times about 50,000 factors is making me concerned about whether you'll get any of that.

MR. HACKBARTH: On this 7,000 issue, not all services are equal in terms of their impact on spending, the volume of care, and presumably what you'd want is a strategy that goes -- invests the most effort in trying to get the high volume, high money stuff right, and less effort on stuff that isn't as significant in terms of the payment structure.

DR. HAYES: A ballpark to think about would be that roughly 600 services account for about 90 percent of

spending under the fee schedule. So if you can use that as part of the design of this, then maybe the job becomes a bit more manageable.

DR. BERENSON: And they're families so that if you actually get some of the key services and a family of services, you can probably fill in the others. I think this -- well, I'm going to be one who, in Round 2, argues that this is manageable. The other observation I'd make to a series of these questions is, this is a relative value scale, so to the extent that you're sort of arguing that a salary practice would be less efficient, more efficient, whatever it might be, it would have to be, Well, they're more efficient in some areas, but not other areas.

I mean, it's good we have to deal with the issue of representativeness, but I think we need to keep in mind that this is about relative values, not the absolute, why are we trying to find absolute dollars like we're talking about in the hospital thing.

I had one specific question. At the last I knew, the RUCs' instructions to the specialty societies in terms of surveying the members to get these estimates were a minimum of 35 physicians? Do you think that that's still

the case?

DR. HAYES: I believe it's 30.

DR. BERENSON: Thirty? Okay, 30. So I think we need to keep that in mind. They can do more, but I think many only do the minimum amounts. So when we're thinking of what we would provide as an alternative, that's sort of the benchmark that we are comparing it against, estimates by 30 doctors who may or may not be representative.

MR. HACKBARTH: So part of the complexity -- I think I was saying the same thing you're saying in a different way, Bob, is that if you look at physicians that are in a multi-specialty group practice that is largely prepaid, and then you try to cost out their per unit of service cost structure, they may be lower cost on a total cost basis, but in producing some individual services, they may be higher cost than the typical practice because they just organize things differently. They put different resources into the practices, et cetera.

So this is really quite a tricky question of which you're trying to measure whether it's just a representative sample of practices or whether you're trying to identify efficient practices in some sense, and if so, what does

efficient mean, on what dimensions, what metrics? Ron?

DR. CASTELLANOS: Just two clarifying issues, and I think, Bob, you almost hit it on the head. Right now we have the RUC doing this now, this process, if I'm not mistaken, and it was initially put in effect in 1993 with the Harvard work? Has it been done since then? I guess the next question is, in 2006 -- I wasn't on MedPAC then -- we asked CMS to look at some of the issues RUC was going and to perhaps review more. Did we talk about time at that time?

DR. HAYES: The answer to your first question, yes, the process that we have now has been in place since 1992 when the fee schedule was introduced. But I think maybe you were asking, has there been some sort of major review, overhaul, research project of the sort that was done at Harvard in the late '80s since then? The answer to that is no, there has not been such, not been such a study.

Your other question had to do with time and the work that the Commission did in 2006. The focus of the Commission's work in 2006 was more, I think it's fair to say, process-oriented. It was talking about use of another expert panel in addition to the RUC to support CMS's efforts. It was recommendations about the kinds of services

that should be reviewed and the frequency with which they are reviewed. But we didn't get down to the point of dealing with time as a concept specifically the way we are here.

DR. CASTELLANOS: Just one more clarifying. I know we want to push it up to the efficient provider, but, Herb, I think I've heard you say this when I was on PPACA that CMS pays for the typical, not the efficient. Is that correct?

MR. KUHN: That's correct, based on what the agency got back from the RUC in terms of the values that they received. So I think that's the way the RUC puts it out for the typical practice.

MR. HACKBARTH: And so, I think this is an open question, Ron, of whether you want to just try to identify the typical, the average practitioner, or whether you want to try to identify something else.

MR. KUHN: Yeah, and it's like the E&M code that he put up earlier when you were talking about 23 minutes. I think that's 99213, is that particular code, and that's a typical practice. But you think about some physicians who might be scheduling 20 people in an afternoon and they're

using that code pretty accurately. So the question is, is it less minutes than that? I don't know.

MR. HACKBARTH: So on Ron's first question, Kevin, what percentage of work values are carry-overs from the original Harvard work?

DR. HAYES: That's a question. Let me see. I'm going to give you an answer, but I'm going to qualify it and say I want to double-check. But I believe that -- bear with me here on this. There are still some thousands of codes that are Harvard-valued. However, CMS has asked the RUC to review those codes and in that process of back and forth between the two, it's been noted that while there are many codes that are still Harvard-valued, many of those are low volume, very low volume codes.

MR. HACKBARTH: So the 600 that you mentioned earlier, the big hitters that really drive the flow of dollars, how many of those are --

DR. HAYES: That I can't answer, but we can find that out.

MR. BUTLER: Slide 6.

DR. HAYES: Slide 6.

MR. BUTLER: So one more time on intensity just so

I understand it. So I understand how the time is calculated from the surveys and the intensity is this kind of triangulation, whatever. I understand, but what I don't understand is how it gets factored into the RVU then. And this doesn't help other than to explain the amount of the RVU, I think, that is due to time versus intensity.

But am I right in the basic principle? If something has an equal amount of time, let's say it takes 15 minutes, then if it is more intense on top of that, it's going to have a bigger add-on to --

DR. HAYES: Yes.

MR. BUTLER: -- create the RVU?

DR. HAYES: Yeah, all other things being equal, you would expect that service to have a higher RVU, the more intense service to have a higher RVU.

MR. BUTLER: And then -- okay, I'll leave it at that.

MS. HANSEN: I'll have another one for Round 2, but just from the standpoint of in terms of intensity and some of the differences between cognitive and procedural complexity, is there any more particular focus now that, say in the legislation, no primary care and, say, geriatrics

were given a 10 percent, just kind of add-on to start to equalize, is there anything intrinsic planned here to really take a closer look at the whole area of E&M cognitive medicine relative to complexity that covers geriatrics as well as primary care?

DR. HAYES: The provisions about mis-valued codes don't explicitly mention E&M services. It's more an issue of validating all the RVUs across the board for all services. And so, then it just kind of becomes a question of how that process plays itself out and what ultimately the impacts would be for E&M services versus imaging versus tests versus what other. So it's a little early to tell yet what the impacts of all of this would be. But the Congress is just saying, we need to look at this, and that's as far as we know.

DR. KANE: Is your question whether they do this specifically for the Medicare beneficiary or any patient? Is that what you're --

MS. HANSEN: Specifically Medicare.

DR. KANE: So in other words, is part of the process here just to look at how much time it takes to take care of a Medicare beneficiary as opposed to, especially, a

geriatric, you know, chronic -- or is it any patient?

MS. HANSEN: Well, my Round 2 is going to be really focused more on the more complex Medicare population.

DR. KANE: Is the idea to look at any patient or just the Medicare patient in the recalibration?

DR. HAYES: The fee schedule is designed to address any patient. It doesn't make that distinction between Medicare versus -- so when services are valued, it may turn out that the typical patient is age 54 or something.

DR. NAYLOR: Which you will need to account for in the study. So I just wanted to, in terms of questions, just for consistency, Page 11 talks about providing a comprehensive approach to regularly collect data from a representative sample of physicians. And yet in earlier parts, you acknowledge that nurse practitioners, physicians' assistants, others, provide and bill for primary care services. So will you be looking toward a representative sample of providers? Yes?

DR. HAYES: A way to think about it would be that it's something -- I mean, this is an issue to be worked out, mind you, but one could imagine this playing itself out in a

way where there would be some consideration of who's furnishing a service and collecting data accordingly, and that that would vary depending upon the service. We wouldn't assume that it would be a one-size-fits-all kind of situation.

DR. NAYLOR: I think we're saying the same thing. We have this growth of nurse-led --

DR. HAYES: Right.

DR. NAYLOR: Nurse practitioner-led managed centers, et cetera. So there may not be any physicians involved in that practice and you would want to include them in your --

DR. HAYES: Absolutely.

DR. NAYLOR: In terms of units of measurement, what do you mean by billable services and practitioners?

DR. HAYES: So you could -- as we discussed, there is a time estimate for each service, each of the 7,000 services in the fee schedule. And so, conceivably, depending upon the availability of data and how the data collection effort is organized, one could go after data specific to each billable service to try to say, well, the estimate for the office visit is 23 minutes. Do we have any

data from patient scheduling systems or electronic health records or what have you, to match that?

Or if that doesn't turn out to be feasible, then a fallback might be, or maybe the better alternative might be to look at a more aggregate level and say, well, okay, how much time per week or per year or what have you are practitioners spending in patient care? And then within that, what's the mix of services that they furnished? And so you could kind of derive an estimate at the service level based on that more aggregate information, conceivably.

MR. HACKBARTH: So I want to ask about a particular type of distortion. Karen described her process of filling out RUC surveys. So Karen, for example, is being asked about services that general surgeons typically provide, I assume, so you get your sample of a few dozen general surgeons filling out this survey and they're being asked about services that they typically provide and, presumably, therefore, represent a significant share of their income. Their incentive, therefore, is to say, Oh, this takes a lot of time. And then the orthopods have the same incentive and the gastroenterologists have the same incentive.

How does the mechanism address that across specialty lines, or is it simply assumed that everybody is -- pardon me for this -- pumping up the same numbers, pumping up the numbers by the same amount and it all washes out on average?

DR. HAYES: So when said the mechanism, you're not talking about the validation mechanism?

MR. HACKBARTH: Yeah, no, I'm talking about --

DR. HAYES: What the current practice is?

MR. HACKBARTH: Yeah, yeah.

DR. HAYES: And I think it's out of that concern that there are calls for this time of validation. It's the risk that there is some bias in the numbers that would prompt one to say, well, you know, just for the sake of assuring good use of taxpayer dollars and such, we need to go through a process here.

MR. HACKBARTH: To the extent that you think that that is a significant risk, then that leads you to the track that we talked very generally about the last time we explored this subject of, you know, if you want the time for a general surgery, just to pick on that area for a second, then you want it unbiased, why not go to Kaiser Permanente

or Group Health of Puget Sound and get the times from them? Not representative practices, but there are practices who are untainted by motivations to distort the information.

Now, the complication, I guess I see, is that, as I said earlier, those practices are organized differently, and as a result, they may not be typical in the amount of time and the relatives may get skewed in that way. So there's a real, sort of, pluses and minuses to that approach.

MR. KUHN: Now, this would be the case on surgery, but it would be harder in other areas. But at least in surgery, you have the OR logs that you can go to. If I remember right, in the early part of last decade, health economic research looked at the in-service time and did a report that CMS has posted on its website that validates it. At least for surgery, you can get pretty darn accurate with those OR logs so you can capture that data anywhere across the country pretty easily.

MR. HACKBARTH: That's helpful. So, I guess, part of what's rattling around in my head that I haven't quite come to grips with is the talk about new surveys on the one hand versus alternative methods of data collection on the

other. And so, in the paper, we talk about, well, having a standing panel that maybe we'd pay for information, but if it's still survey information, it's potentially contaminated by these incentives. Whereas, alternative approaches, whether it's looking at OR logs or going to Kaiser Permanente, you're breaking out of the survey mechanism altogether.

DR. HAYES: That's what I was, probably not very articulately, what I was trying to get at when I said external data sources. You just want to look for something outside of the valuation process that would serve as a source for that.

MR. HACKBARTH: Okay. Let's go on to Round 2. Karen?

DR. BERENSON: There's probably about 10 or 15 things that we could talk about that would illustrate even more the "arcanery" and the complexity here and, frankly, we're not going to fix all of those. And so, trying to look at this at sort of a big picture level, I would suggest that a lot of this, as you've shown, Kevin, is driven by the times. Time is a finite number. Time can be measured.

I think, Glenn, you were just alluding to the

point of where do we get sources of time data that weren't collected knowingly to yield a comparative payment. And I think that that's a very fruitful area because if we can just get time right, intensity is so fuzzy, and I'll be happy to talk to anybody offline about all the things that go into that, but just for a minute think about the intensity of an emergency trachiostomy. You want that to be really high. You want to pay me really well for being able to get that done to you pretty accurately in a couple of minutes.

So on the other hand, there are some procedures, manipulating your anal sphincter, that you really want those to have a high intensity because you'd like to be continent at the end of them. So, I mean, there's a lot of issues here in intensity. Okay? So you really don't want to go there. So time is the measurable thing here.

So I think maybe rather than us creating a whole new mechanism of practices in this and that, we are best served by trying to say, What might be the features of databases or whatever that would help give us accurate times, and look for ones that didn't collect this. And so, once again I'm going to be on my V.A. thing.

The V.A. has electronic records. The V.A. more closely approaches a Medicare population. I mean, they're collecting those times regardless of who uses them and so, why not start to tap into data bases like that and the stuff that was identified by the HER study that, you know, Herb mentioned. I think that's where the money is here in getting something done that will look at sort of the biggest pieces of the puzzle, is going to be through this. And the V.A. system is going of to have all kinds of clinics times. I mean, it's just going to have all kinds of rich stuff. It's much closer to a Medicare database.

I think the other place that potentially could be of value, and I think Glenn, maybe you were alluding to this, is the issue of cross-specialty comparison. There probably is a fair amount of accuracy within the fee schedule, within a given specialty's codes that they do most often. It's when you get to the comparison -- and that's where Sharon and them really didn't have, in the end, a good defensible mechanism for just a whole host of reasons.

The RUC uses a thing called the Multi-Specialty Points of Comparison list, and so you have to have some services off that list that everybody gets to see. So even

though I'm rating a general surgery service, on there is going to be some information for me about the high level E&M service. It might be a procedure from another surgical discipline, some things for me to try and cross that divide.

And if we're going to look at really validating a subset of services in some way, it ought to be the things on the Multi-Specialty Points of Comparison list. Again, that's the biggest bang for the buck in playing out, trying to get the relativity right.

And then the last comment I would make is to Jennie, your question a little bit and the direction you're going. Do you remember in the 2007, I think it was, implementation of the five-year review, that there was a very large increase in the intensity assigned to valuation of management services? And then subsequent to that, the practice expense methodology also revisited, resulted in a relatively greater E&M increase.

Now, we can debate whether it's where we want to be, but there have been a couple of specific things that looked at that. And then the last thing would be, as you think about this, within an evaluation and management service, and I'd like to say that surgeons do some of that

cognitive work, too, there are levels within the service so, as Herb alluded to, a Level 3.

So if I see a sicker patient who takes more time, has more things to manage, just like Tom, I can ratchet up the level of the visit. When I do an operation, I don't have a good mechanism for the outlier patient. Okay? Other than putting a modifier on that seldom gets paid. So that there are some differences in flexibility in the system based on the category of service. And that's not meant to emphasize surgery or detract from medicine services. It's just a fact of how the schedule works.

But again, I think where the bang for the buck is in this process is alternative sources of time data and, if you're going to look at some wholesale validation of services and their relativity, it ought to be the things on the MPC list because that's what the specialities in the RUC process have said, these are services that we think are as close to right as they get.

DR. STUART: One follows Karen with a certain trepidation here because she obviously knows this very well. But I did want to, before we get to the V.A. and some other alternative services, I think there is something to be said

about what the value is from surveys. Bob raised this. He asked what the number was and it was 30 and then went on to say, Well, it wasn't "generalizeable."

I'd just like to point out that in statistics, there is this, quote, rule of 30, which says that if you have a random sample and the sample size is about 30, then the relative standard error should be pretty stable. Putting that in English, it means that the estimate that you get should be pretty close to the population estimate.

But if you move away from a random sample, it doesn't matter how big the sample is. You're not going to get anything. But what it could say is if it were a random sample of 30, and this gets to Glenn's point, if you had a random sample of 30 within a specialty or a subspecialty, you could get what I would call reliably biased estimates.

In other words, they would capture realistically what the mean point is in terms of what these people are actually saying, and that could be useful because after all, it's a relative value scale, not an absolute value scale.

DR. BERENSON: I mean, I agree completely with the statistics around 30. My concern is the randomness of it and whether we know whether -- my sense is that some

specialty societies work very hard to get sort of a random group of practitioners and others probably use a set of physicians who are doing this and know what the game is. And so, I don't know, but I assume there's a lot of variation in that.

DR. DEAN: I certainly have -- actually, first, a question that probably should have been asked in Round 1. My understanding is that the instructions that come with the E&M codes are that time is not a factor, at least we were told that at one time. There is an element of the instructions that say within -- that if that visit is mostly due to counseling and something else, there is a time scale.

But beyond that, it's based on the complexity of the history, the complexity of the physical examination, the complexity of the decision making. And my understanding is that we were not supposed to apply it because there's so much variation in how quickly each -- a range of practitioners are going to be able to get through that thing. Is that correct? Karen maybe can answer that.

DR. BORMAN: I think you're mixing apples and oranges a little bit.

DR. DEAN: Could be.

DR. BORMAN: Because what you've just described is coding instruction and documentation guidelines and that your service is based on key components, which is, as you've describe, history and physical, decision making and complexity of the data.

In the process for valuing a service, it does take into account the typical time to do it. It's a different measurement that goes in the survey process. Time is being used for two different things in those areas, so time is explicitly asked for in the RUC process and in the value assignment process and the Harvard process. Whereas, you're talking about time as used in the coding process is a way different thing. That's to separate out like a Level 3 from a Level V. You don't use time necessarily, but that's different than how it's used. It's just two different systems.

DR. DEAN: But each one of those codes, the 99213 versus 4 versus 5, is tied to an RVU, isn't it?

DR. BERENSON: To an RVU with a typical time, because again, the RVU is reflecting the typical service. So the fact that if you and another practitioner saw the same patient and it took you 20 minutes and it took them 45,

there's got to be a way to balance that out. So instead of awarding it only on time, it does it by the work that you document. This is a complex thing. I'd be happy to talk about it a little bit more. But to the extent that you can trust me, which I realize is a stretch, it is two different systems.

DR. DEAN: No, I trust you.

DR. BERENSON: For two different purposes.

DR. DEAN: You've sort of made my point. It's so confusing. I guess my frustration with the whole process comes in, just, as it's applied to different services that I provide. If I see a patient that would qualify for a Level 3 office visit that has two or three problems and a certain degree of complexity, if I sew up a simple laceration which is much easier, technically, I'll bill the RVU for that. It's about twice as much. And if I happen to take off a skin lesion it goes up again. And if that lesion happens to be a skin cancer for which the procedure is exactly the same, it goes up again. The procedure for a small skin cancer would probably be worth three, four, or five times as much as that office visit even though from an intensity point of view, at least from my point of view, it's a far

easier procedure. So that's my frustration.

MR. HACKBARTH: Kate's next. We are basically at time for this session already and it's the sort of topic that could probably eat up all of our available time. So I'd ask people to keep that in mind and keep us moving so we can get on to SGR.

DR. DEAN: On to the easy stuff.

MR. HACKBARTH: Right, right.

[Laughter.]

DR. BAICKER: How come you always make those announcements right before I'm about to talk?

MR. HACKBARTH: Because I know you'll be responsive.

DR. BAICKER: Good answer.

MR. GEORGE MILLER: Usually it's me.

DR. BAICKER: So it seems as though information based on physician surveys is destined to have a couple of problems, selective response, who's actually filling out the survey, and then strategic answering. Among those filling out the survey, some gaming of the system, which means there are some problems that I think would be impossible to get around with self-reports, although that doesn't mean self-

reports aren't useful. I'm intrigued by some of these possibilities to marry them with administrative data or data from other sources that aren't subject to the same kinds of gaming.

For example, if somebody were seeing only Medicare patients, you could see, do the times allotted for the things add up to 73 hours a day based on the volume that's going through? Now, people are seeing patients from groups where you don't have claims data, and so how do you back out the share of time that is reasonably accounted for. Maybe you need some survey information about what share of your patients are from this pool versus that pool. Maybe you need VA data, some other source.

But even to be able to benchmark and say, these seem plausible, not plausible, the physicians from the administrative data will have a differential enough mix of services that you could then run a regression and see which services popped up with how many minutes, if you assumed everybody was working 12 hours a day or whatever the right number is, and that would give you some validation even though you would still need some survey data to supplement.

DR. KANE: Yes, I just want to remind people. I

think it cost over $5 million originally, in 1988 dollars. So I mean fixing this is not -- and that was just trying to set it up, to get the part that Congress then changed all around, and policymakers had to act on for years afterwards. So it's actually pretty complicated.

But it seems to me I like the idea of not surveying again because I think it just gets you a lot of data that you don't trust, and it's a lot of money to do it, and a lot of people get engaged and get annoyed.

But there are two things I wonder about. One is whether we have all the right codes because it seems to me there are a lot of services people have complained about that they provide, that they don't have any code for, and maybe that would be a fruitful thing to look at in terms of reforming the system.

The other thing is that in talking with various physicians about how they measure their activity levels it sounds like there are lots of national databases for benchmarking productivity, down to the level of if all you do is mammography here's how many of these you should produce in an hour. That's the kind of data I think would be useful to sort of use to test against whether the time

estimate is right.

But time is just one of several of the things that I think are problematic with the whole system, and so putting a whole lot of time in just fixing that I'm not sure is doing to be -- I mean like surveying people. I'm just not convinced whether it's worthwhile. In other words, I'm voting for the idea of looking for other ways to validate the data like the national data sets.

MR. KUHN: Just a couple thoughts on the time-motion study, one is CMS has done this before. At least they've done it for SNF payments when they were refining the RUCs, but of course there were only 54 RUCs versus 7,000 CPT codes. So it was a little simpler, but it was complex.

The other thing that might be helpful, at least for me, as we think about these data options out there, is as I recall from the MMA when we went from the AWP to the ASP pricing the people that were, or the practitioners that were impacted the most were oncology. So the effort was made in order to raise those oncology, or those infusion, codes that were out there. In order to accelerate that process, as I recall, I think some of the pharmaceutical manufacturers actually paid for time-motion studies within

the oncologists' offices in order to get better information to feed to the RUC, so that they could make the recommendations.

So one of the things we might want to do is find out a little bit about that process, what occurred then and is there anything that could help us in terms of formulating a good way or a bad way, or does it really pay off to go with the time-motion studies.

DR. BERENSON: Yes, just a few points. One, I agree with everything Karen said and especially, not especially, but I think the potential of looking at the BA as a source of information. Especially if we were going to sort of do a feasibility study of whether we have alternative sources before we go to substituting the current method, it might be a very easy way to get some information, to see where the gaps are, what, how reliable the data are. I don't think we'd ever want to rely just on BA data, but I think it could be a source.

The second point I'd make, and it hasn't come up, is that in my conversations with RUC members they're not opposed. They've actually been looking themselves at how they could strengthen their own process and not rely just on

these surveys. They haven't seen it feasible to collect, do a major data collection around times.

We haven't talked about how the times would be used, whether CMS would use it directly or whether it would be fed to the RUC for its own deliberations, but I think that this doesn't have to be seen as something contrary. It actually could improve the current process that the RUC is involved with.

In particular, a couple of people have pointed to the problem of very high frequency, short time interactions. You mentioned chest x-ray. Reading a chest x-ray, the professional time was five minutes. If it turns out it's four minutes, it's only a 20 percent error, but it could be hundreds of millions or tens of millions of dollars. And they don't have a good way of validating five minutes versus four minutes versus six minutes.

So I think whether we think about this in we're going to do all the codes or whether perhaps we look to see where the biggest gaps are or where the biggest problems initially.

So I guess where I'm leading is there might be a role here for really doing a good feasibility study of

moving to this alternative.

And the final point I would make is this is one where I would say let's not have the best be the enemy of the good, not to get into what are all of the places that we need to have as representatives. Right now, we have a process in which we don't have good standardization, in which 30 doctors are getting to determine time.

The RUC does throw out some of this stuff. Some things don't pass face validity in terms of time. So I'm not saying that we're just deferring to 30 self-interested doctors, but that's what we've got going now -- is a process that has flaws, and so I think we could find a better one that uses data.

And to your point about $5 million, we are spending $70 billion, $70 billion on physician services. Now it seems we could invest a little bit more than just relying on essentially free labor from specialty societies to sort of validate the key part of all of this, which is time. I mean there are aspects of it, but time is a key part of it.

DR. CASTELLANOS: Very quickly, I think the law of PPACA asked us to do this, and I think our Committee has

always had the responsibility to pay appropriately, and that's what we need to do. So I think we should look into this.

MS. BEHROOZI: Kevin, thank you so much. Scott says this isn't something he deals with. Boy, I have no familiarity with it, but through all your careful explanations some shapes are beginning to emerge through the fog.

But besides the specifics that everybody who knows a lot more about it are talking about, I just wanted to sort of take a step back, be a little bit of an outsider to it, a little heretical maybe. Reflecting on the word "value" in this context, it's kind of different than the bargain basement version of value that we were talking about maybe people respond badly to. It's certainly different than the value that we're looking for in purchasing, right?

It's just a term that's been used for a very long time. This is the way it's always been done. I understand, as Ron emphasized, PPACA asks us to do this.

Kevin, you put a lot of time into this. I don't mean to blow it up. But this is really a very top-down provider-centric view of value. It's what takes the doctor

longer, what's harder for the doctor to do although, as Tom says, there are some distortions in there, even with respect to what it takes a doctor longer to do or what's harder for the doctor to do.

But from the patient's perspective, there's no relationship to value.

And Nancy brought up maybe making some new codes.

I'm jumping around a little here, but I just want to refer back to the paper, Kevin, where you noted that there are some studies that show that time estimates for E&M services may be high. Well, what does that mean? Does that mean doctors aren't spending enough time on E&M? Well, then maybe we need to make new codes in the E&M area like for some of the things that we have decided are valuable or could be valuable, like shared decision-making activities. Right?

One of the responses when we were talking about shared decision-making, Ron in particular was saying we don't get paid for this stuff. Well, maybe we need to introduce new codes. Maybe that's getting out of this box.

I know PPACA has put us into this box somewhat, but I think that what we run the risk of doing, with so-

called validation, is actually codification or further institutionalizing and reinforcing things that are not of value to the patients and, yes, not the right direction to go in.

MR. HACKBARTH: I think this is an important point that several people have raised. I think when we open one of these doors into the physician fee schedule it's always worthwhile to remind ourselves and remind people who watch us that we're focused on time here. There's no pretense that this is a solution to all issues in the physician fee schedule. We're just trying to focus in on one particular problem, or set of problems, and see if there's a way that we can make an incremental improvement with a reasonable investment of resources.

The issue that you raised is one of the most fundamental and ultimately important issue: Is the right way to pay physicians based on just trying to measure the input costs that go into producing a service as opposed to the value of the service to the patient and society? That's a huge issue and arguably one that we need to come back, but it's sort of beyond the scope of poor Kevin's project right now.

MS. BEHROOZI: I understand. Sorry. The last thing I meant to say and forgot to say, then on one of the more pragmatic issues that have been raised, is I think that it would really be a mistake not to be looking to efficient providers. Yes, using everybody in the mix. So we can have that influence, that tweak, at least we should go there.

MR. GEORGE MILLER: While being budget-neutral.

MS. BEHROOZI: Always.

MR. BUTLER: So my only brief comment is if the surveying process is going to continue I don't believe in voluntary surveys or surveys incentivized by finances. You are inherently suggesting it is not random, and it doesn't make any sense to me.

MS. HANSEN: I think other people have expressed some of my sentiments and concerns really well. I would only underscore and turning it back to ultimately when, Glenn, you said this is a big question of value, and I think it is a segment that we have to address.

I want to just take that example and say we spoke earlier this morning about ACOs and that one of the outcomes was, for example, preventing unnecessary hospitalizations. You don't get a code credit for doing that kind of thing.

Another kind of pure demographic that all of you know, that I always come back to, is just understanding who these 30 are and how many of them are dealing with what is the future population of Medicare, that's growing so rapidly and actually where the money right now is being truly spent. And that is people with several morbidities and use of medications and complexity, that if we don't get it right by just tweaking I think we will have done a huge disservice both to the beneficiaries but also to the providers.

Your example, Tom, of the fact that you're seeing a patient with three, four conditions and all of this, and then for you to be able to remove a skin tag and get paid three times that amount, there's an injustice there. That, I think, is not a word technically I would use as a Commissioner. But when you do that, so it's not a surgical procedure that you can do in two minutes to save a person's life. Of course, we want that. That is cognitive work.

But there is something. The misalignments right now need a few core, basic anchors to take a look at. And it's not about doing the perfect. It really is. But still it's doing the right stuff.

So this is beyond my technical capacity, but I

just think of this loom of population, who they represent. And bottom line is I don't want these people who have this, and all of us who are going to be faced with multiple conditions requiring a little bit more time, finding that my doctor wants to do a skin tag removal and not talk to me. So that's kind of the sense of the beneficiary and why the Medicare program was set in the first place, to not totally impoverish everybody.

So this is probably a request that I have both of the Commission, my Commission colleagues, and others to just kind of remember where we're going with population and the work we still have to do, albeit very hard, and not saying one is better than the other except that people have to hopefully get some sense of credible service that's safe, affordable and make sure that the cost curve is appropriately regarded in that process.

I apologize, but I get -- you can tell this is just something important to me, that people will get services appropriately and not get shunned just because they happen to be complex.

DR. NAYLOR: Very briefly, when I first read this intro para about misvalued services, I was thinking about

our state and the spread of the medical or health home in which we are adding technology, adding personnel for care coordination, really trying to grow these practices. And I thought but they would also meet probably the definition of misvalued. Now I realize we're talking about the 7,000 or 600 services, so totally deserved.

But I do think this notion of piloting feasibility, even deep dives, a qualitative look at what's happening to practices really would be important early work in trying to figure out what is the best way.

And a focus on total labor input, not just physicians alone, because there is such a redistribution of work going on. To capitalize on the contributions of everybody, I think that would be important.

MR. HACKBARTH: Okay. Kevin, have we given you enough help?

[Laughter.]

MR. HACKBARTH: Okay. Our last session today is "The sustainable growth rate system," and Cristina is our next victim.

MS. BOCCUTI: I'll try to be quick, or as quick as I can. So as most of you know, policymakers are facing an

extremely difficult challenge regarding Medicare's payment for physician services in the future.

Under current law, Medicare's fees for these services are projected to decline more than 30 percent over the next few years, as required by the SGR.

So for this last session today, I am going to give a brief background on the sustainable growth rate system -- affectionately known as the SGR -- and I'll be covering the basics just to bring everybody up to speed on the topic and then discuss also why the costs are so high. Then I'll raise policy issues associated with the SGR and discuss selected proposals for alternatives to it. And then, finally, of course, you'll have time to discuss these issues and possible future work.

So first, a quick definition of the SGR. The SGR is the formulaic method for annually updating fees for physician services based on expenditure targets. It was designed to keep aggregate Medicare spending for physician services on a sustainable trajectory -- that is to say, in line with growth in the nation's per capita GDP.

GDP was chosen as a measure of national affordability, so when the nation's economy grows, so does

the SGR target. But when GDP is sluggish, the target is proportionately lowered.

The SGR was established by the BBA, but expenditure targets have been a part of the physician fee schedule since it was first implemented in 1992. And let me also add that when I say "physician services," I'm talking about services that are on the physician fee schedule. Of course, other providers do bill off the fee schedule, and they would similarly be affected. These include nurse practitioners, physical therapist, et cetera?

So how does the SGR system work? There are three major steps that CMS must follow annually to determine updates for physician services:

First, CMS calculates the year's SGR target, which is the amount of cumulative spending allowed up to that given year. It's based on four spending allowances: per capita GDP growth; beneficiary enrollment; inflation in practice costs -- that's shown through the MEI; and changes in law and regulation that affect volume.

In the second step, CMS compares the cumulative amount that was actually spent to the SGR target that was calculated in Step 1.

And, third, CMS sets the update for the subsequent year. If actual spending exceeds the target, then the update for the subsequent year is reduced. The reverse is also true; if cumulative expenditures are less than the target amount, then the subsequent year's update is higher.

In fact, if you look again at Step 1, you see that the formula does, in fact, allow for an MEI update explicitly if spending comes at or below the target.

So people often think of the SGR as a volume target, but all I've really only been talking about expenditures. So where does the volume fit in? Well, of course, in fee-for-service, as you know, spending growth is very closely tied to volume. As I mentioned, the SGR formula does allow for volume growth that can be attributed to the two factors of growth in the number of beneficiaries and law and regulations -- such as a new benefit that may incur more volume. It holds other volume growth tied again to per capita GDP.

And price -- the other factor in calculating total spending, of course -- is allowed to grow at MEI, as I just talking about.

So what updates has the SGR produced? In early

years, volume growth was below per capita GDP, so updates were at or above MEI. But in later years, volume growth increased and per capita GDP slowed, creating an ever increasing discrepancy between actual and target spending. So the SGR has called for rate cuts every year since 2002.

For 2003 through November 2010, Congress has passed a series of bills to override these cuts. The resulting updates have been fairly modest, generally lower than 2 percent; and the next cuts I think are on that slide on the bottom bullet that you can see. Maybe if some people can't see it, I'll say that it's negative 23 percent in December, and then again two more cuts, 6.5 percent in 2011 and almost 3 percent in 2012.

So why does it cost so much to fix the SGR is what I'll be talking about next. Given this widespread agreement that such a deep cut -- and multiple cuts over consecutive years -- can have detrimental effects on access, it seems counterintuitive that Congress has not been able to make long-term adjustments to the SGR to bring it in line with a more realistic schedule of updates.

Well, the reason is cost. Such long-term modifications are extremely expensive relative to current

law, which, of course, contains the future cuts. So, in fact, CBO has scored some options: a 10-year freeze -- so that is, a 0-percent update for 10 years -- is $276 billion in CBO's score; a 10-year MEI update, $330 billion. Of course, repealing it altogether would likely be even more expensive. If such options were in a congressional bill, some would they would need to be offset with other federal spending.

There are two key factors that contribute to these high costs.

First, the formula requires that all previous excess spending be recouped, so this amount has compounded every year that the fee reductions are postponed and will continue to compound with future overrides.

Second, current law is based on the cuts being in place. That means that future fees will drop by 30 percent, and all updates will be based on that cut level. So restoring future fees to today's level must account for this 30-percent difference each and every year that the cuts are overridden.

I'll take a minute to note here also that about a year ago, CMS removed Part B drugs from the SGR

retroactively, so that resulted in decreasing the amount that needs to be recouped, and those CBO numbers that we have up there, they do reflect that regulatory change.

Finally, there are other cost ramifications associated with increasing Medicare payments for physician services. Expenditures under the MA program would increase because the MA capitation payments are tied to the fee-for-service benchmark. TRICARE expenditures are also tied to the physician fee schedule, so when these things are being scored, these are other issues that are coming up. Also, Medicare Part B premiums would also increase to cover these costs. That's not necessarily on the CBO score, but it's a ramification that I wanted to raise.

So this slide just illustrates a little bit what I was talking about regarding these scoring costs. The yellow line is the SGR target, and the spending that deviates from that target yellow line is marked by the gray shaded area.

The blue line is current law, and if the SGR cuts were implemented, spending would be back on target, on that yellow line. However, with an override, say, of MEI, which is what the illustrative example is here, the shaded area would all sum to about $330 billion.

Keep this in mind: The historical overage, that's basically what's to the left of the line. That really comes to about $20 billion, that amount. But then the cost, when I was talking about what's going on in the future and the compounding issues, it's really up to 10 times the amount of what you see in the amount that needs to be recouped.

So moving on to broader policy implications with the SGR. Previous Commission discussions have reiterated several widely held criticisms and flaws of the SGR system.

A main flaw is its inability to differentiate updates by provider. It neither rewards specific physicians who restrain unnecessary volume growth nor penalizes those who contribute most to volume increases.

A second problem is that the SGR does little to counter the volume incentives inherent in the fee-for-service payment systems. In addition to these systemic flaws that I just mentioned, there is widespread agreement that the updates that the SGR formula has produced are problematic, as we have discussed. Again, multiple consecutive years of negative updates could be very detrimental to beneficiary access.

And the other pressing problem that is important

to mention has been the uncertainty about future fees that have been coming up more and more lately. Often referred to as "temporary fixes," legislation that overrides the SGR has been accounting for relatively shorter and shorter periods of time. So while these stop-gap measures have indeed averted payment cuts, their short-term nature is becoming increasingly problematic. Physician organizations and news media have cited provider dissatisfaction, stress, and frustration with this payment insecurity. It's important that we say that. Additionally, these stop-gap measures carry an administrative burden on CMS who's dealing with this uncertainty as well.

So moving on to some advantages that the Commission has discussed in its previous report, while we recognized many of these flaws, the Commission also recognized that the SGR system may be a useful tool for restraining Medicare spending. Even though it has been overridden many times, the SGR regularly alerts policymakers to growth in Medicare spending on physician services. And overriding the cuts entails significant debate and effort from the Congress, and this may not necessarily be a bad thing when you're talking about a lot of money. Also,

keeping the SGR in place may draw attention to health system problems and help accelerate other needed payment reforms.

Next, I'm going to move on to discuss a few proposals that policymakers and analysts have discussed in the past several years.

The first is adjustments to the updates by type of service. The main premise of such proposals is that the formula would calculate growth rates and targets for each service category separately and apply separate updates to each of them. Two pieces of legislation were introduced in the past several years.

The Medicare Physician Payment Reform Act of 2009 created two categories of services that are listed there on the screen: E/M and preventive in one category, and "all other" in the other. It allowed the first category to grow at a rate of per capita GDP plus 2 percent and all others to grow at GDP plus 1 percent.

The CHAMP Act, the last major bullet there, Third, only physician services would be included in the calculation of actual and target growth expenditures; services provided incident to the physician visit (such as laboratory services), would not be included. Like the CHAMP

bill, this bill also allows for an MEI update if the target is met. Finally, this proposal re-based the formula's expenditure targets to 2009 (rather than 1996 under current law), allowing a greater chance of positive updates going forward.

The CHAMP Act proposed 6 categories of physician services, and that was in 2007, a couple years prior. This proposal targeted the first category -- primary care -- to grow at per capita GDP plus 2.5 percent and all the other categories at per capita GDP. Both proposals in their day when they came out carried scores in excess of $200 billion, that portion of the fix. Some of the bills had other components to it.

You've seen this chart many times, of course, but we just thought we'd flash it up there one more time so that everyone gets the sense that there is wide variation in growth levels by types of services, and as you can see, E/M and major procedures have grown the slowest, and imaging tests and other procedures have grown faster.

As you have discussed in the past, a type-of-service component to the SGR presents both advantages and disadvantages to the current, single SGR. It recognizes

that spending growth rates differ, like what I just showed you. It produces updates that are more specific to specialties' volume growth rather than all getting the same update. So it does, in fact, penalize high growth and protect low growth. It creates an opportunity also to boost payments for categories that may be undervalued or underused, and I think that was seen when we saw the two different targets in the legislation before the act.

Service-specific targets present a number of disadvantages, however. One problem is that the approach may not easily adjust for evolving changes in the optimal mix of services that patients receive, and here I'm talking about ideally that these service-specific targets would have to account for changes in the demographics of the population, patterns of illnesses, medical technologies, these kinds of things, because these factors could be associated with some clinically appropriate services crossing over categories. So that would need to be taken into account with the type-of-service alternative.

Another disadvantage of service-specific targets is that they could distort the relative value -- and you've been talking about that with Kevin, so I shudder to bring it

up, but it could distort, again, these relative values that have been by this time so carefully drawn.

I'm also going to mention some technical changes here that we've discussed in the past report. Here we'll talk about two of these. One option is to amend or eliminate the cumulative aspect of the formula which led to the growing "hole" that takes multiple years of negative updates to get out of.

If annual targets are used, excess spending that is not recouped within one year is, in essence, forgiven. This was in place under the VPS, which was the update system in place prior to the SGR.

An alternative to totally eliminating the cumulative aspect of the SGR would be to count a portion of the excess spending, so say, for instance, 50 cents on every dollar would be counted.

Another option is to implement -- oh, yes, so the next bullet down there is talking about the addition of an allowance corridor around the spending target line. This option would relax the precision of the spending target and only trigger a negative update when -- or a positive one, so it would only trigger these changes when the difference

between actual and target spending exceeds the specified corridor, such as, say, two percentage points. So you see my hands are a corridor around the target line, and you'll have to be going -- you get sort of a break in between that.

Next here we have some advantages and disadvantages of these technical changes that I just mentioned. The main advantage of the adjustment is that they would suppress the extent of negative or positive updates and diminish to some extent year-to-year variation. Also, they would retain some sense of expenditure control. However, a disadvantage of these approaches is that to the extent that they forgive any spending above the SGR target, they will, of course, be more costly than current law.

In addition to type-of-service alternatives and other technical considerations, the Congress asked MedPAC to examine SGR alternatives that would allow certain physicians to be exempt from the current SGR target, and I'm talking about our report from a couple years ago -- three years ago. Specifically, the Congress asked us to examine expenditure targets that might vary for physicians in group practices, physicians associated with hospital medical staffs, and physicians whose Medicare expenditures were outliers

compared to peers in their specialty.

The premise of the first alternative is that because research suggests that multispecialty practices are associated with better coordinated care and lower overall spending, they should have a separate target. This policy may reward providers who practice in this style, but only 20 percent of physicians are in them, so policies aimed to reward multispecialty practices, in particular, will seem inequitable and, in fact, have some small overall effect on spending.

The premise of the hospital medical staff alternative is that it holds a smaller group of physicians responsible for the health and spending of the beneficiary population. This is akin in some nature to the ACO concept.

Although the sizes of the units for this alternative would vary substantially, each of them would be much smaller than the current national pool in the SGR, so this alternative would increase accountability.

It is also intended to foster greater collaboration among physicians and hospitals. However, some question the viability of this option because of historical divides between hospitals and physicians.

And, finally, the outlier alternative. Some have suggested that because the SGR is unable to adjust for individual physicians' resource use, an outlier policy could be useful to lower spending in cases of extreme overutilization.

After a year of providing confidential feedback to physicians on resource use, Medicare could begin interventions based on results, such as public reporting, targeting fraud and abuse, pay-for-performance options, or even differential updates based on their outlier status.

The major advantage of this outlier approach is that it would promote individual accountability and would enable physicians to more readily see a link between their actions and their payment.

However, implementation may be difficult if physicians are not convinced of the validity of these assessment instruments. And, also, outliers by definition will affect few physicians, so, again, it minimizes the total savings from this kind of alternative.

And here we have this slide here to discuss another option that came in the 2007 report. Commissioners explored the concept of a broad expenditure target

encompassing all of fee-for-service Medicare. This was Path Two in the report.

This approach allows for more flexibility in setting targets among different settings and types of services. And it is also more equitable among all provider types, so physicians are not the only ones under an expenditure target.

Obviously, this broader expenditure target system carries many of the same risks as the SGR system -- namely, being too removed from individual providers to create the appropriate incentives for efficiency. In this regard, an overlay of ACOs may offer some structure for improving the equity and efficiency of a broader expenditure target.

And, finally, on this final slide, I raise a few issues for your discussion:

First, whether or not you want to revisit the issue of modifying the SGR formula. You will, of course, work in the coming months on the physician update recommendation along with all the other sectors. In past years, MedPAC has typically recommended a modest positive update for physician services.

If you want to explore SGR modifications, moving

to the second bullet, which ones do you want to examine? And, particularly, are there any that go beyond the 2007 report? Keeping in mind, of course, that Congress will continue to face the scoring considerations that I raised.

Thank you.

MR. HACKBARTH: Thank you, Cristina.

When we do our round one clarifying questions, and then I have a few thoughts to offer. Any round one clarifying questions?

DR. CHERNEW: I believe this is true, but I didn't see it explicitly written. The laws that you talked about, CHAMP and other ones, those actually weren't passed. They were just proposed.

MS. BOCCUTI: Correct.

MR. HACKBARTH: CHAMP passed the House.

MS. BOCCUTI: Passed into law -- they weren't passed into law.

MR. HACKBARTH: Yes, CHAMP passed the House, never passed the Senate.

DR. MARK MILLER: Just to make a comment to make a point. The 2007 report had more options. We're not trying to take anything off the table. We're trying to highlight

things that people seem to have talked about since then, "people" being the Hill.

DR. CHERNEW: And this discussion is not about how to -- all of these are going to require filling the budget hole from the past accumulated or whatever. This is just about what we would replace it with.

MR. HACKBARTH: Well, I'll touch on that when we get to the round two, but let's do the round one clarifying first.

MR. BUTLER: All right. I'll be the one to appear to still be dumb, but page 8, I just want to understand it one more time now, what happens here, because this kind of says it all, in effect. You said there's a $20 billion gap on the left-hand side, and then you inject, you know, the mandated reduction there, and so you recoup all the $20 billion in that triangle?

MS. BOCCUTI: No, more than that. The recoup is still what's on there. So none of what's to the right is recouping. That's just future -- the difference between a cut update and the MEI update.

DR. MARK MILLER: Cristina, he's asking a different question. Let's say the SGR [off microphone]

stayed in place. I think that's what you're asking. Would that little dip capture the previous overrun. Is that your point?

MR. BUTLER: Yeah.

MS. BOCCUTI: Are you saying dip, the current --

MR. BUTLER: Let me answer, for crying out loud.

[Laughter.]

DR. MARK MILLER: If I threw you off, just reset, because I thought that was your question.

MR. BUTLER: Okay.

DR. BORMAN: It's everybody else's question [off microphone].

MR. BUTLER: Okay. So then repeat what you were all just saying.

[Laughter.]

DR. CHERNEW: I think the answer is yes.

DR. MARK MILLER: Let's assume his question for a moment, let's just assume his question is you have that overrun in the historical period, then you have that little dotted line. What is -- don't assume the MEI to the right.

MS. BOCCUTI: Oh, right. Was that your question?

MR. BUTLER: Yeah, in the first year, you know,

whether it's a 21-percent or up to a 30-percent cut, are you trying to in that one year recapture the entire gap on the left side?

MS. BOCCUTI: In the three years, yes.

MR. BUTLER: In the three years.

MS. BOCCUTI: Right. So by the time you get back -- you know, if you follow the dotted line, you get back in 2013 there, you're on target and you've recouped --

MR. BUTLER: Okay. In the meantime the MEI keeps going, and you're still creating gaps in the future that are not corrected by just that three-year correction.

DR. MARK MILLER: If --

MR. HACKBARTH: Once you get back on --

MS. BOCCUTI: Target.

MR. HACKBARTH: So once you get back on target, then the rules apply, and you look at the expenditures, and that governs what the maximum update can be.

MR. BUTLER: Okay. I understand now.

MS. BOCCUTI: You start back at zero.

MR. HACKBARTH: You've hit the reset button, and you're back at zero.

MS. BOCCUTI: But -- well, go ahead. No, I'm not

going to say the "but."

MR. HACKBARTH: So to be clear, if volume grows rapidly, you could end up with updates that are substantially below MEI, that stay on the line once you have gotten back on the SGR line.

DR. CASTELLANOS: This is a difficult subject, without any question. Just a clarification. In the material that you sent us, in the briefing material, under the issue you mentioned that the Medicare fees were projected to decline more than 30 percent over the next several years. It's actually in three months we're going to have a 29-percent cut. It's not three years, several years, but we have the 22 plus the 6 on January 1st, so the physician community is looking at, in cement, almost a 30-percent cut in three months. And I just wanted to clarify that.

And then can you turn to page 9, Slide 9? This is just a clarifying question. One of the things doctors like about the Medicare system or used to like about it, it was reliable and predictable. You knew you were going to get the money and it was there. I got to tell you, these temporary fixes have cost CMS a lot of money. Do you have

any estimate on that?

MS. BOCCUTI: No.

DR. CASTELLANOS: And do you have any estimates how much it has cost the physician community?

MS. BOCCUTI: No.

DR. CASTELLANOS: I think that would be helpful to know, because we've had four temporary fixes this year, and it is really impacting from a business viewpoint how I run my business. Thank you.

DR. KANE: Back to 8, Slide 8, so in that -- what started happening in '01, I think it is, is not just that volume went up, but that I think the economy kind of didn't grow as fast anymore. I mean, one way to fix this is to get the economy to grow faster.

[Laughter.]

DR. KANE: But then when you -- you know, I mean, part of what's -- I think overall, I mean, there's really two questions here, you know: How do you make good payment policy? And then how do you dig out of a bad hole? But maybe we should also think about, on the first question, how do you make good payment policy, whether growth in GDP is the right metric for saying volume is going to stay below

it. And whether it is or it isn't, is a one-year -- is the growth in any one year the most meaningful thing? Or should there be some sort of an averaging so that it isn't as crazy as this?

MS. BOCCUTI: I think it was in MMA, it became a ten-year moving average. It wasn't from the start, but we have now a ten-year moving average.

DR. MARK MILLER: [Off microphone].

DR. KANE: It doesn't throw it that far off anymore, but it --

DR. MARK MILLER: [Off microphone] But it still does --

DR. KANE: Okay. So I guess maybe then that part's been resolved, but is GDP growth the best metric for really trying to determine how much volume and intensity per capita should go up or not, or can we find a better metric that's not quite so arbitrary? I'm all for affordability, but I'm also for something that makes sense, that's implementable. So I don't know, that's just a separate -- can we think about other metrics by which per capita growth and volume we think is the right amount.

MR. ARMSTRONG: Okay. A little bit more on this

slide. I'm asking this in part because I've been dwelling on some of the same questions you were just raising, but it seems--I still don't--I think I get it, but so the medical expense index, or the inflation rate on the costs that create the gap is a function of several things, but volume is one of them.

DR. KANE: [Off microphone.] It's just inflation.

MR. ARMSTRONG: It's just inflation?

MR. HACKBARTH: [Off microphone.]

MR. ARMSTRONG: So actually, that's where I was going with my questions.

MS. BOCCUTI: It does -- okay. What CBO, when they score this, they make assumptions about volume. So there are volume assumptions in what's portrayed on this slide. But your question was about -- so this isn't just MEI. This is what we think the spending would be if MEI updates were put into effect for each of these years.

MR. ARMSTRONG: So is that driven by a projection of volume of services on a per capita basis influenced by demographic changes?

MR. HACKBARTH: Yes.

MS. BOCCUTI: Well, it's a total spend. These are

total spend numbers. But what's incorporated into that and what's used in the assumptions are per capita numbers.

MR. ARMSTRONG: Okay. I mean, we talk about how we've got an underlying payment structure that incents volume, right, and so that will influence our projected volume. But to me, that's different than volume driven by an aging population or other demographic changes, and I assume that we just kind of throw that all into that projection.

MS. BOCCUTI: [Off microphone.] Right. So here, this is -- this really encapsulates a lot of, I think, what you're saying. So when they're talking about the target, when there's a target and it's calculated, the volume is allowed to grow to account for a bigger number of beneficiaries in Medicare, okay. So we're not holding -- SGR doesn't hold the target against those --

MR. ARMSTRONG: [Off microphone.] -- more and more --

MS. BOCCUTI: Exactly. And also, if there's any -- so that enrollment, and then the last one, if there's a new law or regulation that, say, covers more services or other benefits, that's also allowed. So the target will

completely adjust for that.

DR. KANE: But it doesn't adjust for the change in the age or the chronic disease burden of the population that goes into Medicare.

DR. MARK MILLER: Except that it has the allowance for the GDP on top of the underlying factors --

MS. BOCCUTI: But that's --

DR. KANE: [Off microphone.] -- that's your second -- if GDP --

MS. BOCCUTI: It doesn't account if they were sicker, but it accounts for the number.

DR. MARK MILLER: Well, and just to be -- it's not so much put in to be a proxy for that as much as it's an affordability issue, which is if this is how much society is growing, or, you know, then this is how much you have to afford.

MR. GEORGE MILLER: Mine is more an academic question. Slide 12, please, and this is just an assumption. If all of the services grew at the same level or all service was down where E&M and major procedures, would that have a significant impact on Slide 8 or -- yeah. That would be my question.

MS. BOCCUTI: Right.

MR. GEORGE MILLER: How significant -- would we still have this problem, and then if we still would have the problem, then this is a growth issue, which was part of this discussion that was just asked. And again, it's just an academic question because it is what it is right now, but we have a bigger problem and solving the problem is, as Ron said, very complex and I think if we go back to Jennie's comments, we'd need to start with the beneficiary and how to solve this problem for the beneficiary, because this is going to be an access problem. We have disgruntled physicians all over America. As I travel around, I hear this all the time.

So I don't have the easy answer to this, but this is a problem. And even -- and my speculation is that even if the growth was down where E&M and major procedures, we still may have a gap with the MEI over the SGR target, I suspect. So we've got a -- saying the obvious, we've got a problem.

DR. DEAN: I suspect I know the answer to this question, but do we have any idea, looking at, well, up from Slide 17, the idea of really focusing on the outliers, do

you have any sense of how big a component that is in this whole issue? I mean, it's appealing in the sense of try to focus the pressure on those that are responsible for the changes. On the other hand -- and my understanding is that we were beginning to do this. I mean, they were trying to measure and report physician resource use and so forth. I've --

MS. BOCCUTI: Well, there is some of that work going on, and you might want to be able to talk to John Richardson, who's been following that, later if you want to get more updates on that.

With respect to being on the outlier, you know, it depends on where you draw the line of what the outlier is. You have -- you know, if it's two standard deviations away and -- we ran the numbers on this, and I don't want to misspeak on the numbers, but, you know --

DR. MARK MILLER: We can get those --

MS. BOCCUTI: Yes.

DR. MARK MILLER: -- because we did a little bit of sensitivity with that stuff in the --

MS. BOCCUTI: I did it.

DR. MARK MILLER: -- and I couldn't drag it up,

but we have this.

MS. BOCCUTI: Yes.

DR. MARK MILLER: We can get it to you guys.

DR. DEAN: I guess I was wondering, you know, is it something like patient utilization resources, where it really is heavily skewed to one end of the spectrum, or I suspect it's probably much more broadly distributed. Is that --

MR. HACKBARTH: I wouldn't think it would be as skewed as the patient distribution --

DR. MARK MILLER: Or to put it differently, so you get some impact. You shave a bit off of your expenditures, but it doesn't solve like --

MR. HACKBARTH: And in the bargain, what it does mean is using tools like episode groupers for purposes of payment policy, which is something that we've been a little reluctant to do because we're not quite sure that they're sufficiently refined tools, so that's another aspect of it.

DR. STUART: This is a transition between round one and round two. I hope you'll allow me to do that. I'll be brief. And it seems to me that there are two big issues here. One is this $330 billion or $220 billion or whatever

the number is, and frankly, I just don't think that's our business to figure out how we can fill that. That's Congress's issue, and with all due respect, Ron, I agree this is a real problem, but we're not going to fill that hole. I mean, we could say, let's eat soap. Let's get rid of this thing and start fresh. And here, I think we can really have some impact in terms of talking about going forward. And I'm just afraid that if we focus our attention on this big backlog, which in many ways is a fiction, which the Office of the Actuary and CBO itself recognizes, that we'd be better off as a Commission.

DR. BORMAN: Would you go back to the growth graph again, Cristina, with the BETOS categories. Yes. Could we -- or, I'm sorry, I misspoke. The one with the MEI and -- Peter's favorite graph. Could we potentially at some point see the segment of the economy that is health care services plotted along that, as well? And the reason I'm asking a little bit about that is GDP was in there in the formula in part to do some sort of equating to worker productivity. I mean, Bob Reischauer taught us all that any number of times, I think. Okay.

But I think sometimes we forget the growth engine

that health care, rightfully or wrongly, has -- you know, we may not have done it in the right mix, but it has been a huge economic engine in our country. And it would just help me to know a little bit about what the economy did to be able to say this was a fair trade-off, this GDP equalizer a little bit.

I don't want you to reward me for inappropriate volume, but I think as you start to talk about this, it's a lot more -- there's a lot more underneath it than just physician behavior if one in every eight or every six workers in the country is employed by the health care industry. We move around a lot of stuff here when we talk about changing the physician fee schedule by virtue of their activity as small business owners, and I'm just looking for something, and maybe that's not the right graph measure, but something that helps me retain what's the contribution of the health care sector to our overall economy, if that kind of makes sense.

MR. HACKBARTH: So let me pick up with Bruce's comment. Bruce said a lot of things that I've said before and basically agree with, namely few, if any, people believe that Congress is ever going to cut physician fees

sufficiently to get us back on the SGR line. And I dare say, nobody has believed that for quite some time. And so in that sense, as Bruce says, we do have a fiction here. The score attached to this is not believable to most anybody at this point. And that's been true for a while.

Now, having said that, there are people who have still said, well, maybe this isn't a bad device to have, and Cristina mentioned some of the arguments that you hear in her presentation. For one thing, it's made it politically feasible to have lower updates and lower Medicare expenditures than what likely happened in the absence of SGR. So even though we're way over budget, looked at within the SGR framework, it has helped slow the rate of increase in physician spending in Medicare compared to what would have happened absent the SGR. At least, there are a lot of people who believe that. I think there are some countervailing considerations, but there are a lot of people who believe that.

A second argument that you hear is, well, if we are going to give this up, if we're going to take some budget hit, whatever the exact number is, we ought to get something for it, and so we ought to use this as a lever to

move the system in a better, more sustainable direction for the long run. And so just go to the Congress and say, let's just wipe the slate clean and go forward. That's the sort of response that you'd get from them.

DR. STUART: I have no qualms at all about getting something from it. No, absolutely. I'm right on board with you.

MR. HACKBARTH: Okay. So we've been basically muddling through now for a number of years with these short-term fixes, and some people, at least, have been content with the short-term fix approach for the reasons I just mentioned. This is helping to hold down fee increases and we're keeping this tool in the closet that we may be able to use later on to leverage the system in a better direction.

So a key question for us and for the Congress is, why not continue the muddling through strategy, and my sense is that the costs of muddling through are growing, and perhaps growing rapidly. There are all the issues that Cristina laid out so well in her presentation about the distorting effects of this and physicians are out buying the imaging equipment to offset the fact that the fees are low and maybe ordering more tests than otherwise would be

necessary as a response to this extreme pressure on price. And so those have been problems for a while now. And also the specialty, the differential impact by specialty has been a problem we have been suffering with for a while now.

But my sense is that on top of that, there's a new sense of urgency coming from the fact that the extensions are now very short-term. So we're having these painful debates that Ron referred to, not once a year or once every couple years, but they're happening every six months or even more frequently than that. And the fact that they're happening ever more frequently means that the price that we're paying in terms of physician confidence in the Medicare program and patient, Medicare beneficiary confidence in the program, I think is destined to rapidly increase.

And the bad news of this is the price tag for repeal or substantial alteration obviously does nothing but grow more rapidly, and to the extent that you're in a PAYGO budgetary world where you have to find offsets, the pressure is going to be for shorter and shorter extensions, because the price tag of every extension is growing. So we are caught in a vicious cycle that I think is going to be very

damaging for the program, for the confidence in the program among beneficiaries and physicians. Muddling through, I think, is going to come at an ever higher price.

Now, we could say, oh, this is all funny money. Just repeal. Hit the reset button and let's do a redesigned system. My sense is that the likelihood that we're going to have a constructive impact if we do just that is minimal. We may feel good as a result of it, but I don't think it's likely to persuade many people.

So let me just finish, Bruce, and then I'll hand it over to you. So if we really want to make a difference, as opposed to just make ourselves feel better that we've made a recommendation, I think we have to listen carefully to some of the issues raised by the people who have been reluctant to let this go and see if we can come up with a recommendation that, if not eliminates the whole, tries to reduce the adverse budgetary impact of this, even though we may not think it's real money, and accomplishes some goals like using this as a lever to advance system reform that has some support on the Hill.

And so I'd like to see if we can focus on a really constructive proposal as opposed to just a feel good

proposal, and that means applying some constraints to ourselves and maybe not doing what we would do in a perfect world, but something that could make a difference on the Hill. So that's my two cents worth, and we'll launch into round two, and Bruce, I'll give you the first round two.

DR. STUART: I don't disagree with that. It's just the awesomeness of trying to pay this back. That's the problem that I have. I have no problem at all with having to redesign this thing to have something that has some real teeth in it, to have mechanisms so that we avoid this problem in the future of this deficit growing. Some of that's in PPACA and obviously in our discussions we're going to want to make sure that we understand what we're doing, how that works with the provisions in the health reform bill. But I'm all behind having something that works here.

What I fear is that we're going to end up in the same position that Congress is in, in that we can't fill that gap and so we just push it off ourselves, or that we come up with something that admits that we can't fill the gap, and so that Congress says, okay, well, you haven't helped us out, then. So --

MR. HACKBARTH: [Off microphone.] So let me

provide an illustration and give people a chance to react to this, and this isn't something that I'm necessarily advocating at this point, but just as an illustration.

So you can reduce the budgetary impact to the extent that some segment of the physician population is -- when CBO does its score is going to end up getting less than the MEI. So if the score for the MEI proposal is $330 billion and you come up with a proposal that CMS scores as meaning that some segment of the physician population is likely to get less than a full MEI update, the score is going to be lower than $330 billion. So that's one reason that some people look at the type of service option as potentially a way to go.

What that means is there's going to be relief for some physicians, maybe relief for all physicians relative to this, but more for some physicians than for others. And they use that mechanism as a way of limiting the scoring effect that you're going to have. There are other ways you can do it, as well, but that's just an illustration.

DR. KANE: [Off microphone.] -- a question. So let's just say we say, well, we think we should adopt LCA and it has this kind of saving and that we should maybe have

a negative update for home health and DME beyond what we have recommended -- can those count -- can we just fill the hole the way that -- what is that, IPAP or whoever the new -- can we just start filling the hole now with recommendations going forward --

MR. HACKBARTH: Well --

DR. KANE: And then there's provider --

MR. HACKBARTH: -- the answer is mixed. LCA would be a change in current law and so it would have some score. I don't have any idea how they'd ever come up with a score, but it would have some score. The home health and those things, that money has been spent already.

DR. KANE: No, make it -- no, go beyond --

DR. MARK MILLER: Go beyond --

DR. KANE: No, I said go beyond.

MR. HACKBARTH: Oh.

DR. KANE: I mean, like DME and --

MR. HACKBARTH: To the extent that you go beyond, yes, that can contribute.

DR. KANE: So you can actually -- that's what I was questioning. Are we stuck with saying -- does Congress say, I only want to hear physician only fixes, or can we

just start pulling where we think there's excess payment and say, let's fish --

MR. HACKBARTH: I think the answer is that we could cobble together a broader package that includes some things that affect physicians and some things that affect other providers, so long as we are not double-counting.

DR. MARK MILLER: And I just want to make one other connection in your mind, and I haven't said this out loud in front of Glenn so it may be retracted, but the other linkage is people were saying get something for it. You can think of that in two ways. You can think of some grand compromise of people sitting around a table and say, okay, if we pull this back, then this is what happens, and that may be part of our discussions.

But the other way to think about it is think about institutionalizing an incremental process. This kind of goes to, like, the linkage to the ACO. So if providers step out of the ACO, they're out of the SGR, and you sort of hollow it out, if you will. You probably cannot solve the problem that way, but as one of the elements that might be an array of choices, you can think about it that way. And in a sense, each time you get a block of providers to step

out, you've gotten something for what you're trading off at a conceptual level.

Of course, whether it saves money or not will depend on how well the ACO is constructed, which was our this morning's conversation, but assuming that actually saved money.

DR. DEAN: Just quickly, I would really agree with what you said that the cost of putting this off is skyrocketing, both in terms of dollars, but even more so just in terms of the psychological impact and the frustration and hostility Ron referred to. I mean, this really can't continue or this whole thing is going to be much more difficult.

I guess just to speak to the specifics, I mean, there's some appeal to focusing it on -- or to dividing them up into different types of services, but you're still stuck with the same thing, that what the individual does is not going to be affected. I mean, it's still -- within any of those groups, you're going to have a spectrum. You're going to have the big users and the cautious users, and I think you're still stuck with the same problem. So I --

MR. HACKBARTH: I agree with that. That's a very

important observation. So one of the things that we learned from this SGR experience is these sorts of high-level aggregate systems are totally ineffective in establishing appropriate incentives for utilization. In fact, arguably, they create perverse incentives to do more to offset the future price cut.

Having said that, some proponents of type of service would say, well, you do it not for the incentive effect, but for two reasons. One is to reduce the score, and two is for equity reasons, that you want to build in an automatic mechanism that will increase the fees of some types of physicians versus others. And so it's not for efficiency. It's for relative value reasons in reducing the score.

DR. BAICKER: It seems like a lot of the discussion about the value of the SGR hinges on its value as a threat, that is it a bigger threat that keeps the unobserved counterfactual spending in check because it would be so big and because it has to recoup so much extra money, does that make it a bigger threat, or does it make a smaller threat because everyone knows it's so unrealistic that it'll never come to pass, and maybe if there were something more

realistic, that would actually be a more plausible threat to keep spending under control. That hinges on counterfactuals that we can't observe, so I don't know how to answer the question, which are people going to respond to more, the bigger threat that you're not going to implement or the smaller threat that you might implement or might not.

None of that addresses the fundamental question of is it a good idea to have an automatic adjustment based on aggregate spending that is based on a formula that looks exactly like this, and I don't know whether we even want to have that debate or not, but it's not clear that that moves us necessarily towards efficiency as well as the whole realm of other options we haven't talked about.

MR. ARMSTRONG: Just generally, I would want to agree and affirm that the costs are higher than we can bear and that we really need to look at some way of confronting this.

Glenn, I really appreciate the way you were framing kind of a combination of evaluating policy and politics and other variables as we kind of go through this. I have no idea what the answer is, but I really like the prospect of being very clear about what at a very high level

are the goals that we have, the policy goals that we have, and to ask how offering some solutions to this problem might create really great leverage for us to advance a series of other goals, many of which I know are also scorable, but just don't get brought into this conversation in the way that we could gather them a little bit more effectively.

I think the last point I would make is maybe random and irrelevant, but in my role running a $3 billion company, one of our big issues has been to connect the top level outcomes for the organization as goals that could be deployed throughout our system so that decisions that I can't control actually are made independently by thousands of people, but all in pursuit of a single common organizational goal. I mean, it just seems that here we have a system where we have set these broad-level goals that are completely disconnected from the goals or the incentives that get deployed throughout that system.

And that might just be a way of thinking about how we leverage this huge, complicated, pressured debate about this overall set of goals into a more rational description of how our various policies are kind of aligned and trying to pursue the same goal.

DR. KANE: Yes. I'm just -- I'm trying to be a little practical about this, although I think it's hard to be practical, but maybe we should think about whether there's some way to chop this up into different time frames so that it's kind of manageable, like, okay, for the next three years, we're going to have the physicians take a zero update and we're going to collect the rest of the needed shortfall in these other buckets, and then sort of at least try to say, okay, there's a target, but we're going to impose it across all providers. The physicians are going to take part of it and the others are going to take part of it, and that'll be in our update discussions, part of what we have to hit. Let's do it a three-year, not a one-year. One year doesn't do anything anyway. You know, a three-year window.

And then say, also, in that three-year period while we're trying to get ACOs in place and all these other things, you know, then we'll try to say the next three or four years, what we'll really be trying to do is have providers move into less volume-enhancing payment models and see if that helps us offset this. But I think we have a short-term and a long-term and the solutions are different

for the short-term than for the long-term.

MR. HACKBARTH: So what I hear you saying is the SGR would stay in the background and what we'd try to do is address it in three-year increments.

DR. KANE: Three-year increments that sort of get -- because we need a little time to get closer to the types of payments to discourage the volume, you know, that encourage medically appropriate volume rather than -- well, we believe some of this volume is inappropriate. I mean, if we don't think it's inappropriate, then we really should change the whole -- but I do believe there's probably volume that shouldn't be provided in our physician spending. So we keep the physicians in a zero update for the next three years, but then the rest of the shortfall, we look for the deep pockets in the other providers. But after that, we say, okay, now the physicians, if they want to get out of the next round of SGR, they have to get into a payment system that doesn't enhance -- doesn't -- you know, like an ACL or medical home. But I don't think you can solve the ten-year problem. I think you can only do it in chunks, short-term, long-term, and they're different.

MR. HACKBARTH: So to help us stay grounded,

Cristina, so trying to do three years as opposed to a complete repeal reduces the score, but even the three-year cost is a big number. If you say, what we're going to do is give people zero or one percent for three years, the score on that will be many tens of billions of dollars --

DR. KANE: You're trying to --

DR. CHERNEW: Unless you take it out in years four to six --

DR. KANE: Unless you take it on the others.

DR. CHERNEW: -- unrealistically.

MR. KUHN: No, but they've already spent --

DR. KANE: You suggest ending a couple wars and you make that count toward --

MS. BOCCUTI: CBO has scored three-year, and if people want more of that, I can give you the link to that. But, I mean, what you stated is correct and we don't need to go into it, but it's just then three years after that, there's a deeper --

DR. KANE: What you're trying to do is get to something you can actually manage instead of just you have to blow off because it's impossible. So maybe it's a minus-one update. I don't know what it is, but there's some

number where we can start to manage that in a three-year window. We can't manage the ten, but we can manage the three and we can distribute the loss across the whole -- in the update process.

MR. HACKBARTH: Yes. I like the concept. Let's think some more about that.

DR. BERENSON: Yes. Cristina, could you go to Slide 13? I want to get into the weeds here while everybody's been at the right level. I want to try to make a third argument for why type of service may have some logic to it, and as I do this, Mike and Kate can tell me if I've got my economics right or wrong.

The second bullet there, and the disadvantages could distort the relative values, I actually think it might improve -- increase accuracy of the relative values in the following sense, that fast-growing services, we do not adjust for volume growth in the way we calculate practice expenses, and that practice, at least some portion of practice expenses are fixed and are being now spread over a much larger volume of services. And, in fact, it's a surrogate for doing more accurate pricing to take into account volume growth.

So that when advanced imaging had slowed down in recent years, but between 2000 and 2006 it doubled in Medicare, and yet we didn't adjust their practice expenses, a lot of which are directly related to the equipment itself, and so by having this sort of -- if we had had a type of service limit with a marginal reduction in payment rates, in a sense, we are trying to adjust for that volume growth. In that case, Congress came along and by legislation reduced the prices, but if we had had a type of service -- now, that might contemplate having below the level of the top six, maybe getting down to -- I'm not exactly sure how to do it, but I guess my question is, Mike and Kate, is what I am saying make sense to you?

DR. BAICKER: I would think it depended on some things that we don't know in terms of why volume was growing in one area versus another. Was it because it was getting better and therefore the price should actually be going up because it's getting -- there's greater demand for it, I don't know, and the spillovers between the different types of services, if one is growing faster than another and then you separate out the prices, it depends on which things are positively correlating whether you've made it better or made

it worse.

DR. BERENSON: I don't know about better, but aren't we saying that the costs of --

DR. BAICKER: Now Mike --

DR. BERENSON: I mean, isn't the average cost, in fact, coming down?

DR. CHERNEW: I think because it's not -- the imaging growth hasn't been because an imaging center is just doing tons more, but there's more imaging centers.

DR. BERENSON: Well, there's both going up.

DR. CHERNEW: Right. So the extent to which you're getting more imaging centers entering in different ways, you're not getting that effect.

DR. BERENSON: No, that's right.

DR. CHERNEW: So it depends on how much the expansion is new entry with different cost structures versus old entry just with an economy of scale.

DR. BERENSON: No, I understand.

DR. CHERNEW: And you have to think about how the other services, and so --

DR. MARK MILLER: Let me give you a different argument to try and make his point. I wouldn't have gone

with the practice expense. I would have said this. You see all this volume. It must be that what we're assuming about the time it takes to do that service is wrong.

DR. CHERNEW: So I think that the things that are growing are they ones that were really profitable, and so by de facto, that's an indication that we're overpaying. You could then adjust --

DR. MARK MILLER: [Off microphone.]

DR. CHERNEW: But if you think the ones that are growing are growing because we have figured out technically that these are actually really good things and we're not -- then you have a different view, which I think is what Kate was saying.

MR. GEORGE MILLER: But you also have issues like Mary brings up. You've got some of these practices adding mid-level practitioners that allow them to see more patients, and that also is driving up --

DR. MARK MILLER: [Off microphone.] That means the physician is spending less time.

DR. BERENSON: Yes, but in fact, the volume growth is not in E&M services and it's not in major procedures. It's in these other categories --

MR. GEORGE MILLER: Like imaging --

DR. BERENSON: -- and those are the ones, I think, that would be subject to a type of service limitation, and -- no, I get your point, but this isn't really fine-tuning. This is basic. In a sense, we're saying it's a volume discount.

Now, the point about there being more people doing it, I understand, it's not perfect, but I guess what I'd argue is we should work through the type of service pros and cons, but I actually don't think we have to view this as, oh, we're now distorting relative values as if we do have this sort of gold standard that we -- I think we need to discuss it more, but I think it could actually be improving accuracy and shouldn't be viewed as a penalty, can be viewed as sort of a volume discount, something like that.

DR. BAICKER: But you would need to know something about the substitutability versus complementarity of the different services and how you're changing their relative prices to know if you're making it better or worse.

DR. CASTELLANOS: Just a couple points. One is Nancy brought up the GDP, per capita GDP, as the benchmark or what we think is affordability there as a country.

There's no question, when the economy grows, it looks good. When the economy goes into the tank like it looks now, it doesn't look good. And it's hard to tell my patients that according to the SGR, the economy is not doing good, so I can't order as many tests. I mean, that's what you're asking me to do. I'm not doing it, but that's what you're asking me to do.

Can you go to Slide 12 for a second? The point at the retreat was that we do have data from 2008 forward showing some improvement by things we've already done, and I would really appreciate having that data available on slides when it is available, and Kevin, in some communication I've had with him, saying that he thinks he can accept the AMA RUC data. So it does show that we have some improvement on imaging and some improvement on all services, and some of the things we've already done is working and that's the point that I'm trying to say, and that data is available and it would be nice to have that available.

Can you go to Slide 10 for a second? You know, Congress either has to be hard of hearing, blind, or dumb not to understand the only advantage of this is it lets policy makers know what's going on. I don't think that. I

would much rather have a slide up there that says the disadvantages of the SGR and I don't see that. One, it hasn't worked. And for 20 years targets haven't worked. And unfortunately, it's forced some behavior changes.

You didn't have this slide available for this, but in our package of Slide C, the actual update since 201 that I've had as a physician is about 2 percent. Now, the cost -- of course we don't have cost data, but if you look at CMS, they tell us that the costs have gone up about 22 percent and if you look at MGMA, they say around 44 percent. So if my costs are going up and my payments are staying the same and I'm a businessman, obviously I have to do something. I either have to close my business down or you're forcing me to do some behavior to pick up the difference.

So let's go. What are some of the solutions? Well, I don't have a good solution with a gap, but I do have a solution, and I can only talk for myself and a few doctors I've talked to. I think if you pay my costs and allow me to make a small profitability, I would be happy. If you pay my costs and you gave me some profitability.

What are going to get for it? Well, the same

thing you hope to get for the ACO, a behavioral change. I can't promise you're going to get a behavioral change from the ACO, but I'm hoping we can and I'm hoping that if we do something constructively with physician payment, we make institute a behavioral change. This system is not going to work until you have doctors working with you.

MR. HACKBARTH: Ron, I need to raise one point with you. While it's true that the increase in unit prices paid by Medicare have not gone up as rapidly as the Medicare Economic Index. It does not follow from that that physicians are losing money. The revenues that physicians get from Medicare have been going up, and although they have moderated slightly the rate of growth in those revenues from Medicare has moderated slightly in the last few years, that's after many years of very rapid growth.

I just don't think it's a fair or accurate characterization of the economics of medical practice that physicians are just losing money. The revenues are going up. The data on physician incomes, the bottom line, the take home, those numbers aren't plunging, and for many specialties, they are doing very well indeed

DR. CASTELLANOS: Glenn, I couldn't agree with you

more, but where is that difference coming from? It's not coming from the services I provide. It's coming from the ancillaries that are built in or I'm forced to build into my practice.

MR. HACKBARTH: And there I think there may be an area of agreement. But again, the profitability of medical practice is not plummeting, as your comparison of MEI and updates would suggest. That is just not a complete picture of the --

DR. CASTELLANOS: I'm sorry if you got that message. The message that I'm trying to give you is yes, we are profitable, but why are we profitable? Perhaps because of some behavior modifications that --

MR. HACKBARTH: As I said, we agree on that.

DR. CASTELLANOS: -- that we were forced to do.

MR. HACKBARTH: Well --

DR. CASTELLANOS: And I'm saying with the ACO, hopefully some of these modifications, behavior modifications will change, and I'm hoping that -- and I think physicians, for the most part and I can't talk for everyone, that I think if we got paid fairly, and we're getting paid fairly and you keep up with our costs, I think

we would be happy with that. I don't think we need to continue to increase -- and I'm not saying it's inappropriate volume, but it certainly isn't increased volume.

MR. HACKBARTH: So let's emphasize that area of agreement. I think one of the potentially bad byproducts of SGR has been that it's distorted medical practice and it's resulted in more rapid increases in some services that may not be particularly value for Medicare beneficiaries

DR. CASTELLANOS: That's right.

MR. HACKBARTH: Cori?

MS. UCCELLO: I am persuaded by the idea that some type of target system is a useful tool and can provide Congress some leverage. Where that sweet spot is, as Kate said, it's kind of unclear except it's clear we're not at it right now. So when I looked through these different options -- and Cristina, I thought, did a great job of putting all this together -- a lot of them made a lot of sense to me and seemed to be moving things in the right direction.

I think where I struggle is that because the problem is so overwhelming figuring out how to combine different options that make sense together -- because we're

talking about there's not going to be one specific thing that's going to solve the whole problem. So I just think we have to make sure, when we're putting packages of things together, that it makes sense.

MS. BEHROOZI: I think somewhat picking up on that point, Cori, I guess I'm feeling like -- poor Glenn suffered all that abuse when he said there isn't one way to fix the SGR, and it's just sort of no less clear now that you can't really fix the SGR for some of those reasons like it doesn't get at individual behavior and all those things. So I kind of return to Arnie Milstein saying, Leave the SGR in place so that we can drive people into the better systems that we are working on, coming up with. Not just us here, the 17 of us sitting around this table, or the staff, but in all these other places that health care reform is going on and whatever -- by the way, I wonder how many physicians have been driven into Medicare Advantage by the pressures of the SGR. I don't know. It might be something to think about.

But anyway, we would hope that you could use it as a stick, still leave it in place, except, obviously, as Cori said, as everybody is saying, it's beyond the tipping point of being ridiculous now. It's not working anymore. But I

think that's the only reason, really, to, quote-unquote, fix it, not because it can be a good tool, but just because it's got to stop being a ridiculous thing.

But then you've got to deal with the scoring issues. So yeah, I guess what I'm arguing for is sort of lowering the standards for judging how good the fix of the SGR is, you know, not excepted to do too much. I like the type of service regime because maybe Bob's not all the way right, but it does a really good thing in adjusting -- you know, doing good things to the relative values.

But it's not necessarily bad. It might have a little corrective effect. It's not too bad and I feel like that kind of ought to be more of the standard that we're looking at while we're trying to do really good things and everybody is trying to do really good things in developing a reformed payment system. So between here and there, kind of modify it and it will never be great.

MR. BUTLER: So three points. One is Part A and lessons learned, not that this is old stuff for many of you, but the DRG system, can you imagine if we didn't have that what utilization would look like on a per case basis? And it's -- and on top of that, not only have we got the unit

pricing under control, even the utilization, the admissions per capita has some things, whether admissions criteria or re-admission rates, it's a model that should say, Well, if everybody behaved in that way, we would make some advancements in the system. It doesn't mean there can't be increased pricing and so forth. That's point one.

Point two is again on George's Line 12. So if you think about that -- and we've said it and I'll just say it again. I think what we're really thinking about is the things maybe not just above the E&M code, but that's primarily the focus that we're talking about.

So how do we kind of group that activity in a way the DRG does, and we can't wait for episode of care and everything to make all that, but how do we group that activity above the trend line of E&M, in particular, to incent that at a lower level in the short run, not just in the long term reform scenario.

Now, while I say above the E&M line, I'd note that that E&M line maybe has some churning in and of itself. It's gone up 10 percent per capita. So there may be some opportunity there.

But now I'm back into my third point, which is

Bob's, and I think there are real pricing opportunities above the E&M line to make an impact and a deposit, if not fix, some of this, and I'm thinking ahead even to our December kind of January updates thing.

Now I'll go my third point, which is really also consistent with Scott. The average physician is on the cusp. If you came along and said 10 percent in the E&M code, that's their world, and they're thinking, I'm not taking anymore if that's what I have to take for an E&M code. They're not sitting there saying, If you cut my imaging or ancillary tests, then I'm bailing out of Medicare. I think it's primarily at the E&M. That's the focal point.

And so, that's where we have some sensitivity in terms of accessibility, I think, that we would have to worry about. Again, it just kind of makes me think there's opportunity on the pricing above the E&M code line on this chart and less so on that. That's just the realities of the world if we're trying to get at the grassroots' level physicians to be on board with what we might propose.

MR. HACKBARTH: And that's consistent with what our access data shows, that to the extent that we have

access problems, they're in primary care. I know E&M encompasses not just primary care, but more broadly. But right now, access to specialty services does not seem to be as difficult as primary care.

I want to make sure I understood the first part of what you were saying. It sounded to me like you were, by drawing your analogy to Part A, you were saying that you would look at bundling or packaging of services with E&M like some imaging services.

MR. BUTLER: That would be terrific. Any episodes help do that. Any of those would help. But I'm also trying to think practically, like even in the next year or two what might you do while you're trying to get those bundles together, and I think that there's opportunity on the pricing side of the ancillary and the testing as also an interim tool to use while you're trying to get the bundling and those things together.

MR. HACKBARTH: Jennie and then Mike.

MS. HANSEN: Just to confirm the short-term focus that we could probably do some real specifics, but going back to your comment about the bundling and other kinds of things that so much of this is related to these other pieces

of work that are the backdrop of maybe the longer range land of “incentivizing” is toward the positive direction.

And I think just one final closure with the point that -- the example that Tom gave, because we have a whole another area of where graduate medical education is going and why people choose dermatology, with your example, over internal medicine, general internal medicine and others.

So these things are so -- you know, it’s like they’re so linked, but they’re just the pragmatic point of doing something real specific in the short term that begins the shift of directionality would be, obviously, the practical thing to do.

DR. CHERNEW: First, a response to something Ron said about income and the amount of tests you can order, and I guess I’ll say just bluntly, because at the end of the day and maybe the tape has run out, to pretend that national income has nothing to do with what health care services we can afford over time, I think, is just folly and I wish it weren’t so clinically.

But it just happens to be the case, that if we had enough income, sure, we wouldn’t have to worry about a lot of things. But we don’t, so we do, and it’s not good to

have to follow the economy throughout the business cycle, but over the long run, we do have some constraints that are related to national income. If we had more income, we'd have less constraints, and that's an unfortunate aspect of economics.

In response to Bob's comment, I think volume growth is just one indicator, and I think the idea of type of service is still going to be very blunt because we don't know, within these categories, for example, what parts are good or what part is bad. I guess if I really had my druthers, and not necessarily opposed to type of service, I would make a deal with the medical community in general to say, We have a problem with the fixes.

We have to hit some target, whatever that's going to be, so let's have the RUC figure out what type of services within these are over-valued and try and adjust it that way. At least you have someone clinically saying, We're paying too much or paying too -- now, we could do a different version which says, All right, we're going to do it because we're just going to cut all imaging and we're not going to cut E&M. Right? And if you think we can do that better and we want to do that better or someone else wants

to do that better than sort of clinical people that know what's in the codes, that's fine.

I guess we would have to go there because you have to go somewhere, but I guess I would rather not be trying to decide whether I'm going to do more harm or good by picking very broad categories and putting some on some Draconian trajectory and elevating others. But I guess someone is going to have to do it.

So a few things relative to the presentation. I think it's very hard to target specific physicians so I'm kind of opposed to saying, All right, you've used a lot of imaging, we're going to put you -- you know, I think the ACO-type thing gets us there in a broad way, but I'd rather not have that complication.

I think I'm very wary of any recommendation that says if you're in a multi-specialty group you get paid more than if you're not. These sort of site of care differences just create all kinds of implementation problems that I would be really hesitant to get into in that regard.

I might add, just parenthetically, that this makes it very hard in general. The ACO needs to save money relative to the SGR if it's going to save money, which is

incredibly Draconian. So pushing people into the ACO thing is right, but, of course, the more we think we're going to save, in the long run trajectories, if we were scoring this right, we might not save quite that much because the SGR is so Draconian.

But I do think that if you are going to try and let the ACOs be exempted, if you will, one way or another, I think that only works if the ACOs are not paid fundamentally fee-for-service, because otherwise, you just have different fees in the different places. I think the ACOs have to be paid in a more bundled way and then I can deal with the different organizational things. It gets all the incentives, like in Scott's place, right to do that. You've got people looking down.

I think that basically is a reasonable way to go and it just will take some time to try and get that part right. But that's, I think, where ultimately we're going to have to go and it's just a question of how quickly we get there depends on how Draconian they want their target to be.

DR. MARK MILLER: Okay. I don't mean this the way it's going to sound. It feels like all the options were sort of taken off the table. Do you have --

DR. CHERNEW: No. [Off microphone]

DR. MARK MILLER: I didn't think necessarily you were thinking that, so maybe just one more sentence or two.

DR. CHERNEW: I think getting people to the ACOs, figuring out how to do that, and then depending on what target -- you don't want the 330 billion, if you go back to 330, whatever slide it is, so you have to figure out how far -- what target you want within that, how much below you want that to be and then the question is, do we do it by type of service, which I guess we would have to do. That's the best of the remaining ones. Or do we say to some organization that's more clinically oriented, All right, you hit this target by telling us which of the over-valued services based on volume and what you know about the services and what you know about ancillaries, and if you hit the target well enough, then the SGR hammer will come down less because you're doing it service-specific.

The problem with the SGR is it takes all the services, good, bad, indifferent, whatever they are, and it just slashes them all. And so, if there's a target you have to meet because of that, you can either do it in the aggregate or you can pick the specific ones, and the type of

service option is you take them in groups and you can make those groups narrow or broad, and if you trusted the clinical community to hit whatever target right, I would do it through some sort of RUC process, opposed to us trying to do it or say something.

DR. NAYLOR: Honestly, first I think we should operate within a budget, so I don't know that we've talked about this, but your recommendation about having a total Federal spend on Medicare all in, I think, is important even though it doesn't get to the providers directly.

And then what might be some mechanisms as we transition from SGR to being the prudent purchaser, maybe some of the earlier recommendation around if you have a Federal target, are there graded benefits or ways in which we could begin to think about incenting beneficiaries to really go for the efficient effective services in the short term until we learn what we're going to hopefully learn over these CMS demos around ACOs, et cetera.

So it seems to me that we -- I think, though, we should start with a budget that says, This is our target.

MR. HACKBARTH: And so, just as a reminder, one of the features of the Affordable Care Act was that down the

road a little ways, they do establish basically a Medicare budget linked to the Independent Payment Advisory Board process.

Now, it's a complex set of provisions and there are limitations on who can be cut by how much, but that is an initial step towards saying, not just for physicians we've got to limit the growth, but program-wide we need to limit the growth and we need people to advise us on how best to hit those targets. That's the essence of the IPAB proposal.

DR. NAYLOR: Does that prevent us from recommending, over the next three years, that we operate within these parameters in terms of Medicare spending today, plus or minus?

MR. HACKBARTH: Well, it doesn't prevent us from saying that except if we say that, what comes with it is the obligation to say what we would change in order to hit the budget.

DR. NAYLOR: Right.

DR. CHERNEW: Not to be over-inflammatory, and I realize I'm going to regret this, but one other approach would be in the line of what Mary said, is to allow some

amount of balanced billing above what Medicare pays and then begin to think through the incentives. So I realize I'm not advocating that. I'm just trying to have a list of things you could do if you couldn't afford Federal funding a certain amount of this money, but you realize if you don't pay this, the whole system may well collapse. And so, I'm not a big fan of allowing that, but you could begin to explore that to solve the whole and some of the problem, and you have to figure out how to do that.

DR. BORMAN: I think one of the things you said earlier, Glenn, is pretty important in terms of trying to specify what we get for some longer term relief or change or whatever it might be, and I've been struggling to think about what, in practicality, some of those things might be.

And so, I think one of the things that I remember Bill Scanlon constantly telling us is, that we don't full advantage of the notion of getting data back. We pay out a lot of money, but we have this sense that we can't require people to give us more and better information. And yeah, there are some practicalities about what you can report and all those kinds of things, but we keep coming back to the notion that physician fees are the one thing that doesn't

flow through a cost report kind of mechanism.

So maybe one of the things is to tie it to starting to get the kinds of data that we think we might lead us to better estimates and better projections, number one, and maybe targeting some of the meaningful use criteria towards those kinds of things as well, because I think also, as Bill pointed out to us, a fair amount of that information is known to physicians about their practices through other mechanisms, because it also starts to get at some of these things about income from other sources and whatever that may, if we could parse it out, kind of help us understand this a little better.

I think another thing might be that we agree to an acceleration of the time frame where P-for-P or resource utilization or some of those other things start to go on a compressed time frame to the withhold category as opposed to the bonus category. I'll probably need a remote car-starter after having said that.

But I think if we are -- there's no question that physicians are part of this problem and we control, to a large degree, some parts of this problem, but we need to be able to identify some things that we can contribute back, in

turn, for getting some stability, which I think at the end of the day, whatever we do needs to come out with some three to five year stability. The unpredictability. We're just kind of not getting there and I think there are some trades that would be reasonable to ask of the physician community.

And then if you go back to the type of service category graph, while I would agree that that line above is the richer target, I would point out that some of us folks down in the lower lines kind of are the ones that order some of that stuff on the top line. And so, maybe there needs to be a little but if negativity for a lot of ordering.

I mean, to just penalize the people who do it without sort of coming in some way at the folks who order it -- and granted, I'm the one who's talked about at the end of every advanced imaging report is about the next test you should get in order to see something better, and that's not good. But lots of do it and then turn around and order it. So I think it's a two-part problem there and we just need to be a little careful about that.

MR. HACKBARTH: That's a really important point. That's the appeal of directions like ACO. So as opposed to arbitrarily manipulating rates to types of services or types

of physicians, it says, Let's move towards more organization and collective responsibility for producing results for patients. So that's, to me, a way more sensible way to go. The problem is that that doesn't do anything to reduce the $330 million, or at least not anything significant -- 330 billion. Excuse me.

DR. BORMAN: But my point on that would be that as you think about what do we need to take out of imaging, that maybe some of it -- there's a portion of it that comes out of the deliverers of the imaging service and maybe there's some little piece of that that comes out of the people that ordered it. That's what I was getting at. I realize it doesn't solve the 330 billion.

MR. HACKBARTH: I don't think we're home yet. I don't think we've figured out how to solve this yet. But this is a good start and thank you, Cristina.

We'll now have our public comment period. Let me remind you of the ground rules. Please begin by identifying yourself and your organization. Limit your comments to no more than two minutes. When the red light comes back on, that signifies the end of your two minutes. And as I always do, I'll remind people that this isn't your only or your

best opportunity to community with the Commission. I urge you both to be in direct contact with the staff and to take advantage of our website where there is an opportunity for people to file comments as well.

MS. TODD: My name is Laurel Todd. I'm with the Biotechnology Industry Organization. My comment relates back to the first presentation of the afternoon on Least Costly Alternative, and I promise I'll be quick because I, too, want to get home.

So we represent a membership who spends billions in research and development to bring novel therapies to the market every year. And as you're not surprised to hear, we have a particular interest in LCA discussion. As I said, I'll be brief. We appreciate the opportunity to comment here, and we have also met with the Commission staff and appreciate that opportunity as well.

We agree with the conclusion of MedPAC staff that there's currently no statutory for CMS or its contractors to make Least Costly Alternative determinations. Congress chose a very specific reimbursement methodology for drugs and biologics in the Medicare program by moving from AWP to ASP. The methodology is widely seen as accurate and

effective and should continue to be followed.

This is a competitive market price that takes into account rebates and discounts necessary to compete not only within Medicare, but also those discounts achieved by private market negotiations. It also reflects the generic and multi-source pricing based on FDA determinations of those characteristics.

Moreover, there are a number of potentially innovative payment methodologies that Congress drafted CMS to explore through PPACA and efforts should focus on ensuring prudent implementation of these ideas with a continued focus on quality. Furthermore, there is not currently a process for making evidence-based decisions on the sameness or similarity of particular drugs and biologics outside of an FDA determination that drugs are bio-equivalent, or through the forthcoming process for bio-similars. This is not currently what is evaluated by the CMS coverage process.

So consequently, we do not believe it is appropriate to move forward regarding LCA and urge MedPAC to continue considering the many issues that would need to be addressed before policy recommendation in this area could be

made.

MR. CONNOLLY: Can I use the time she didn't use? Gerry Connolly with the American Academy of Family Physicians. I really appreciated the rich discussion on the SGR today. There's a real popular, somewhat popular vernacular going around called repeal and replace. Years ago MedPAC said repeal the SGR, and I would hope that you would stick with that position. I know that you're getting push-back from Congress that they want something to replace that with and I think today you started to tease through some of the very difficult territory about how to get to that.

Realistically, I think you were talking more about the replacement and the long-term solution, which we're very encouraged by and interested in, but the long-term solution, I think, needs to be laid out to Congress in the near future. I don't think you need to do anything in the short term, by November 30, because I think they're only going to do another patch.

But I think what this organization, this Commission, can do, as an advisory body to Congress, can do something before November 30 and that is insist to Congress

that they hear your recommendation that these temporary patches are doing nothing for the program. They're instilling instability, they're not creating predictability, and they're not creating confidence not only in the physician community, but in the beneficiary community.

Congress needs to hear from MedPAC that these temporary patches, becoming more frequent, are creating more instability and they're not the way to run this program for our nation's seniors. Thank you.

MR. HACKBARTH: Okay. Thank you. We are adjourned until 9:00 a.m.

[Whereupon, at 5:37 p.m., the meeting was recessed, to reconvene at 9:00 a.m. on Friday, October 8th, 2010.]

# MEDICARE PAYMENT ADVISORY COMMISSION

## PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, N.W.
Washington, D.C.

Friday, October 8, 2010
9:05 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
ROBERT BERENSON, MD, FACP, Vice Chair
SCOTT ARMSTRONG, MBA
KATHERINE BAICKER, PhD
MITRA BEHROOZI, JD
KAREN R. BORMAN, MD
PETER W. BUTLER, MHSA
RONALD D. CASTELLANOS, MD
MICHAEL CHERNEW, PhD
THOMAS M. DEAN, MD
JENNIE CHIN HANSEN, RN, MSN, FAAN
NANCY M. KANE, DBA
HERB B. KUHN
GEORGE N. MILLER, JR., MHSA
MARY NAYLOR, PhD, RN, FAAN
BRUCE STUART, PhD
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [9:05 a.m.]

MR. HACKBARTH: Good morning. So our first topic this morning is "Issues related to risk adjusting payments for bundled services."

Carol.

DR. CARTER: Good morning. This presentation is to remind you of past work that the Commission has done on bundling and the recommendations that you've made, and to discuss the requirements in PPACA for a pilot and to begin a discussion about one of the key implementation issues, and that's how to risk-adjust a payment.

Before we get started, I wanted to acknowledge the work that Kim Neuman did on this paper.

The current fee-for-service program does not provide incentives for providers to deliver an efficient mix of services or to coordinate care across settings. Under a bundled payment, an entity receives one check to cover all services delivered over a period of time across all sites of care. Bundling payment is intended to create and align financial incentives for providers to be efficient over the entire course of care, and to improve the care that beneficiaries receive.

Bundled definitions vary in what starts and stops one, the services included and the length of period, or the window. We considered program spending to arrive at a working definition. Hospitalizations are costly for the program. About 20 percent of fee-for-service beneficiaries account for three-quarters of programs' expenditures. More than one-third of beneficiaries who are hospitalized go on to use post-acute care. The analysis we're presenting today uses hospitalization to trigger a bundle that includes all services furnished during the stay and for 30 days after discharge.

Regardless of the definition of a bundle, a key issue will be how to vary payments for differences across patients. Risk adjustment raises or lowers payment to account for differences in patients' care needs. For beneficiaries, risk adjustment is important for ensuring access because if providers are not fairly compensated for all types of patients they may elect to treat some patients and not others, or to stint on services. From the providers' perspective, risk adjustment affords some financial protection for treating high-cost beneficiaries. And for the program, Medicare is protected from making

unnecessarily large payments for patients with below average care needs.

Risk adjustment also facilitates fair comparisons across providers and patients in terms of cost and quality. Without risk adjustment a provider may appear to be high cost or to furnish poor quality, but what's really going on is it treats a complex mix of patients.

Today, we're focused on risk adjustment for payment purposes. Risk-adjusted quality measures are also important, and we anticipate future work on quality measurement.

And now Anne will provide a little background on past Commission work on bundling and what was in PPACA.

Ms. Mutti: So in 2008, the Commission recommended piloting bundled payment for hospitalization episodes. Specifically, the recommendation stated the pilot should be voluntary and that it should for select conditions. And just to give you a little context, we made that recommendation in combination with two related recommendations. One was that providers should be given information about their resource use around a hospitalization episode, first confidentially and then

publically, and the other recommendation was that Medicare should reduce payments to hospitals with relatively high readmission rates for select conditions.

The Commission specifically chose to recommend a pilot for bundling, and this is because it wanted to balance the urgent need to change fee-for-service incentives with the recognition of the operational challenges and potential unintended consequences that can result when you make a major payment change. So just to be clear, when we considered this, we did recognize that not all implementation issues had been fully thought through, and I mention this because CMS will be needing to be thinking about these implementation issues because the recent health care reform law requires that bundled payment be piloted, and that is to start in January 2013.

Much like our recommendation, the legislative pilot is voluntary and for select conditions. It must not increase Medicare spending and is for services delivered around a hospitalization. In general, the legislation defines the hospitalization episode as beginning 3 days prior to admission and extending 30 days after discharge, but the legislation allows for the Secretary to have

discretion in setting that timeframe.

The legislation envisions that multiple models will be tested under this pilot and allows for a range of types of providers to apply to receive the bundled payment. It specifies that one model should involve payment for services such as care coordination, medical reconciliation and discharge planning.

Another model should be the continuing care hospital model, and under that model a bundled payment is made to an entity -- the continuing care hospital -- that can provide a full range of post-acute care services under a common management structure. The bundled payment would cover the cost of the post-acute care services and presumably readmissions, but not the cost associated with the initial stay, the initial acute care hospital stay.

So among the implementation issues that we discussed back in 2008 were exactly how would the quality incentives be designed, how would they be integrated in the bundled payment. What entity receives the payment is another question, and how would we temper the possible incentive for providers to increase the number of bundles they are providing. How would beneficiary choice of

providers be affected is another issue, and how bundling should interact with the notion of ACOs certainly comes to our mind after yesterday's conversation. We're happy to talk about that further on question.

But the issue that we're really focused on here today in this presentation is risk adjustment and how the bundled payment amount is determined, but more specifically risk adjustment.

And Craig will now talk about and present some data on variation across hospitalization episodes that might suggest that just using hospital diagnosis and severity level information alone might not be sufficient for risk adjustment.

MR. LISK: Okay, good morning. I'm now going to show you some data on the variation and use in spending on post-acute care services.

If we look at all hospital discharges, we find that 37 percent of all hospital stays are followed by use of at least one post-acute care provider in the 30-day period after hospital discharge. Use of post-acute care though, as you can see in this slide, differs by diagnosis. Heart failure, 40 percent of the cases use post-acute care after

discharge. For cardiac bypass, for patients who also went under angioplasty, it's 58 percent. For stroke patients, it's 68 percent. And for hip and femur procedures related to trauma which do not involve joint replacement is 90 percent -- near universal use of post-acute care in the 30-day window after discharge.

We chose to show you this set of conditions because they have different characteristics that might make them appropriate for a bundled payment system. Heart failure has the highest aggregate post-discharge spending of any diagnosis. CABG, or bypass operation, is part of the ACE demo which extends bundled payments to the hospital portion of the stay; so it could be an early candidate for expansion to post-acute services, for bundling to post-acute care services. Stroke cases have some of the highest post-acute care spending of any condition. And hip and femur conditions have near universal use of post-acute care.

Across most diagnoses, use of post-acute care providers increases with patient severity, and within severity use of post-acute care is higher for patients who have longer inpatient stays than for patients who had shorter inpatient stays. These differences in use can be

quite substantial. For example, we see a 36-point spread in post-acute care use between Severity Level 1 and Severity Level 4 stroke patients, and a similar type of variation if we look within Severity Level 1 stroke patients in terms of the use for short-stay to long-stay patients. So that's for stroke, for example.

We see this across a lot of these conditions, but for hip and femur case patients, for instance, we do not see this wide variation in use.

These utilization differences in use of post-acute care services are important because uses of PAC services have much higher total Medicare spending in their episodes.

But even among post-acute care users, we see substantial variation in total spending and post-acute care spending. This next slide shows the variation in Medicare spending that occurs within a 30-day payment bundled for post-acute care users. We, therefore, have removed people who did not use post-acute care services.

To show the variation, we take the ratio of the spending at the 75th percentile to the 25th percentile. Please note we are showing differences in standardized payments here -- payments that reflect national rates, not

provider-specific adjustments such as the area wage index or the disproportionate share adjustment. Thus, a patient in Boston will have the same value as a patient in Billings, Montana if they used the same set of services.

In the first column, we show the variation in payments for the entire bundle -- hospital stay plus services provided 30 days after. In the second column, we show just the variation in post-acute care provider spending.

As you can see, the variation in Medicare spending within a 30-day payment bundle varies by condition. For example, if we look at the Severity Level 1 stroke patients, we see a 2.7-fold difference in Medicare spending between the 75th and 25th percentiles, and a 6.7-fold difference in post-acute care spending. But at Severity Level 1 cardiac bypass the differences are smaller -- 1.1-fold difference for the bundle and 1.6-fold difference in PAC spending. Actually, even though you see 1.6, that's a relatively small number; it's less than $1,000.

In general, we see wider variation in post-acute care spending than in total spending. While higher severity bundles appear to have less variation than low severity

bundles, the dollar differences in spending are substantial. So at Severity Level 4, we see it's more than a $10,000 difference in total episode spending between the 25th and 75th percentiles.

Please note that we are not comparing costs here, but variation in payments. So the variation cost would likely be much higher.

One of the drivers of post-acute care spending differences across patients is the setting the patient is discharged to. This table shows that there are substantial differences in post-acute care spending depending on the setting a patient is discharged to from the hospital. So if we look at stroke care, for instance, we see that the average spending for post-acute care services across all stroke patients is $10,680 for users of post-acute care. But for patients that were discharged to use outpatient rehab the spending is $569. For home health, it's $2,500. It's $6,000 more for SNF care. IRF is $10,000 more than SNF. And long-term care being the highest at $22,000.

This spending reflects all post-acute care services that a patient uses during the 30-day window. So the IRF numbers, for example, also reflect spending for home

health care services because frequently patients who use an IRF will also use a home health after discharge, for instance.

The cost of post-acute care, therefore, is related to the setting used. Those that use outpatient rehab have the lowest, and then it progresses on up the scale -- home health, then SNF, IRF and long-term care hospitals.

Although not shown on this table, average PAC spending generally increases with patient severity and patient length of stay. In general, lower severity patients or shorter-stay patients within severity level are more likely to use lower cost post-acute care providers, such as home health care. Higher severity patients and patients who had longer inpatient stays are more likely to be discharged at facility-based post-acute care settings, such as SNFs, IRFs or long-term care hospitals which have higher costs.

Now Carol will talk about risk adjustment for the care needs of patients during a bundle.

DR. CARTER: We saw that spending varies considerably even within severity levels of DRGs, underlining the need to risk-adjust payments for patient differences. In bundles centered around a hospital stay,

the patient's acuity will largely shape spending. However, when a bundle spans a longer period of time, a patient's chronic conditions play a key role in shaping total spending.

In these analyses, we used diagnosis and severity of illness during the hospital stay to examine spending differences across the 30-day bundle. Hospital diagnoses may not capture chronic conditions, particularly mental illnesses, if they are unrelated to the reason for the hospital admission. We plan to expand our analysis to include chronic conditions of patients which should help explain spending differences, particularly across post-acute care.

I should note that no risk adjustment is perfect. The current payment systems accept a fair amount of variation within case mix groups and then how well they explain cost differences across patients.

Risk adjustment generally tries to predict resources required using patient and other characteristics. One of the challenges we face is that current spending on post-acute care does not reflect efficient, or needed, care. Providers have no incentive to consider the downstream

spending over a period of time. In addition, the home health and SNF payment systems favor therapy provision, so current spending reflects patient selection and service provision.

Furthermore, patient placements in PAC settings are not necessarily cost effective. Many patients who need post-acute care can be managed in several different settings. Medicare's conditions of participation do not clearly delineate which patients belong in which settings. In addition, patient placement in post-acute settings reflect hospitals' ownership and contracting relationships, the supply and availability of a bed at the time of discharge, not necessarily patient care needs.

And last, there's a lack of evidence about the best settings for different types of patients in part because there are not comparable outcomes data for all PAC settings.

As a result, spending differences across bundles reflect many factors, some of which have little to do with patient characteristics. So we may be limited in how much of the variation in spending risk adjustment we will be able to explain.

We will start by looking at factors that the current post-acute payment systems consider already in adjusting payments. These generally describe the clinical condition of the patient. All of the PAC services use diagnoses as an adjustor. Because PAC care extends over a longer period of time, they are more likely to capture chronic conditions than hospital coding.

Except for long-term care hospitals, the PAC payment systems also consider the functional status of the patient -- their physical and cognitive functioning. Unfortunately, until these measures are on a common scale, this information will be difficult to use. CMS is currently testing a common patient assessment tool in post-acute settings and will report to the Congress in June of next year. The IRF PPS considers patient age; the home health and SNF PPSes consider service use, home health visits and therapy minutes in adjustment payments, as a way to mitigate stinting on services.

Although service use will help explain spending differences, it can gained by providers, and we've discussed before how these financial incentives drive service provision.

Others have suggested factors that could be considered in a risk adjustment method. However, each raises issues when thinking about the factor for payment purposes.

The first is the presence of a caregiver at home, which affects the selection of post-acute setting and can shorten hospital and institutional PAC stays. Patients who need post-acute care, but who cannot go home, will be more costly to treat. Yet, if we put a risk adjustment method and considered that, it could be gamed by providers.

Socioeconomic status of a patient is another factor that may capture unmeasured differences in patient care costs. These factors are indirectly reflected in some of Medicare's current payment systems. MA plans and Part D plans receive higher payments for dual-eligible beneficiaries. Hospitals receive disproportionate share payments for treating low-income individuals.

Under ideal risk adjustment, clinical conditions would explain much of the differences across patients. So a separate adjustor may not be needed, but we won't have a perfect risk adjustment. So the question will remain: What is Medicare's role in bridging the gaps in health status.

Regional variation and supply clearly affect the cost of PAC care, given high-cost providers -- those are long-term hospitals -- are not located in every market. Yet, beneficiaries living in those markets receive their care in other settings. So it's not clear if supply should be considered.

Practice patterns also vary considerably across the country, and to what extent do we want to consider those in establishing payments.

As we think about bundled payments, we will need to consider other policies that will need to go hand in hand with them. First, we will want to make sure that with a large payment at stake we don't see a big increase in hospital admissions as the way to trigger a bundled payment. One possibility would be to include an incentive payment that would hold providers accountable for unusually high admission rates when compared to entities with similar patients.

Another concern is the unusually high cost beneficiary which would put providers at undue financial risk. Outlier policies would lessen the incentive to avoid high-cost patients or to stint on services once they are

admitted. At the other cost extreme, we need inlier policies, so that unusually low-cost bundles are not paid a full bundled payment.

As with any fixed price, we will need to be mindful of incentives to stint on services. Low-cost outliers and pay-for-performance policies could dampen this incentive.

Finally, we will need to consider policies to smooth the transition from fee-for-service to bundled payments. A transition allows providers time to make adjustments to their practices and cost structures. Blending fee-for-service and bundled payments during a transition is one way to accomplish this.

Over the next few months we plan to investigate ways to measure patients' chronic illnesses that shape PAC and total episode spending. We could also explore design issues such as the length of the bundle or whether we should consider bundles with and without PAC services separately. We could also explore additional risk adjustors. And getting your feedback on these issues would be very helpful, and we look forward to your discussion.

MR. HACKBARTH: Okay. Thank you.

Let me ask a clarifying question. So you presented data that showed variation within a diagnosis and cost, in large part it seems as a result of variation in differences in post-acute care use. That's an important driver of the variation.

What I didn't see in the paper or hear in the presentation is how much variation there is across hospitals. So bear with me, I'm a lawyer. I'm sort of out of my element here, but, you know, when we first instituted DRGs, we knew there was going to be variation within a DRG. That's not inherently a problem if over time it averages out. If a given hospital gets some low-cost patients and some high-cost patients over time, that averages out. It's a problem if it doesn't average out because the patients are not randomly -- the low- and high-cost patients are not randomly distributed. They are concentrated in certain institutions. So you need to look at not just the variation within diagnosis but also the variation across institutions to see if some institutions will be systematically disadvantaged.

Is that something that you've looked at or plan to look at? Or am I just totally confusing myself and you?

MR. LISK: No, that's a good point. We were looking right now just at the patient level and not at the facility level in terms of what the implications are for that.

MR. HACKBARTH: Yes, okay.

MR. LISK: So that's definitely something for us to look at.

DR. MARK MILLER: And just to pick up and go a little bit further, as a lawyer you have really zeroed in on a good point here.

[Laughter.]

DR. MARK MILLER: So let me compliment you on that. Was it real obvious I was playing up?

No, in all seriousness, for everybody, you know, you always risk -- when you look at an individual or an episode level, you're going to see a lot more variation, and then there's the aggregation up to the facility level and sort of looking at -- and that's the point Glenn is making. I would just make two points about that.

One, here in post-acute care, perhaps a little different than the hospital setting -- and you guys drew this out -- there's a lot more ability to sort of pick and

choose. You know, hospitals, they don't have to take everybody who comes, but there's a lot more pressure when somebody presents that you're taking the person as opposed to a post-acute care facility which can do an assessment and say, "I'm not taking this patient." So even if you saw the pattern today, one concern would be going forward what you drive through that.

The second thing and the dilemma of this whole conversation is in order to really understand any of this, you sort of need to risk-adjust the data and look at the resulting variation, and the circular problem here is we're still exploring how to risk-adjust. There's the diagnosis out there, but there's a sensation that there needs to be more than that to capture some of the variation.

So there's a little bit of difficulty of just even walking through this conversation, and I think the point of the conversation is we're starting to look in a couple of different directions and getting feedback from you guys on your experiences and what you'd have us looking at.

Did I do any violence there?

MR. LISK: That was a very good summary in terms of the point -- excellent.

MR. HACKBARTH: More questions?

DR. BORMAN: Is there any way that you can quickly think of that you could get to what's an indirect measure of the physician's level of complexity, which would be the level of service within the coding scheme, so that if this were a Level 3 nursing facility visit or a Level 5, or however many levels within that, if that could be a tracker in some way? It may be way too hard to tease out. There may not be a really good easy data set to merge. But just a consideration might be at least at the time of hospital discharges or something you can come up with that would reflect at least what in theory the physician thought was a relative level of complexity and use that in some way to relate it. Don't know if it's possible, don't know if it would be productive, but just a thought.

DR. CARTER: One of the things we are starting to think about is how we can use the post-acute care data, not just the diagnoses that are there, but also looking at the groupings, because particularly I'm thinking of the IRF. There are comorbidity tiers, and so more complex patients are in different case mix groups. But you're getting me to think about trying to use some of the physician codes as

well for the visits, but we do plan to start looking at what's happening in post-acute care and can we use some of the administrative data to start to sort those patients into groups.

DR. STUART: You guys have done a terrific job here. In fact, it's so terrific that, after I read it, I wondered why anybody would stick their toe in this pond. It's almost daunting in terms of the difficulty.

I have a couple of technical issues that I'll raise in round two, but I would like to focus on Slide 11 just for one minute. This gets back to this question about where do you expect to end up with risk adjustment, because basically this is saying that if it's not efficient care to begin with and your risk adjusters are based on current patterns of care, then, you know, what do you get at the end of the day? And I'm wondering, in light of that, have you looked or do you plan to look at post-acute care patterns in integrated care settings? Because it would strike me that this is where you're likely to get -- well, you're going to get patterns of care that are not driven by the same financial incentives that you're worried about and which you want to risk-adjust to control against.

MS. MUTTI: I know that we've talked about the idea of wouldn't it be great if we could get Kaiser's data to figure out how they handle their post-acute, and so we haven't started on that, but we have thought about it.

DR. DEAN: Could you state again the exact definition of post-acute care? I'm assuming it doesn't include physician services.

MR. LISK: So in terms of when we're talking about post-acute care, we're talking about home health post-acute care providers -- we'll say post-acute care providers, and then we have what is in, let's say, our 30-day bundle in terms of what we did for analysis. So post-acute care providers are going to be home health care, skilled nursing facilities, inpatient rehab facilities, long-term care hospitals, and outpatient rehab therapy. But when we did our analysis, we included all physician services in the hospital stay plus 30 days after the stay, all other outpatient services the patient received during that period, and other Part D drugs weren't included in here.

DR. DEAN: So the graph that you showed of the percentage by diagnosis -- it doesn't have a number. I'm not sure just which one it is. But the fact that 40 percent

of patients with heart failure got post-acute care, I'm assuming they did have physician visits, right?

MR. LISK: That's for post-acute care providers.

DR. DEAN: Okay.

MR. LISK: To clarify, so 40 percent used a post-acute care provider, which would be the ones I listed.

DR. DEAN: Okay. And have you looked at all at the connection between these data and readmission data? Because there is a significant connection -- and, for instance, there was a paper in JAMA just within the last couple of months about patients that had early follow-up visits with physicians had a lower level of readmissions, for instance. And I'm assuming it would tie into this data somehow, but I --

MR. LISK: In terms of when we're looking at the 30-day bundle, we're including readmissions in that, too, but readmissions end up being a smaller share of the bundle. There are some different relationships between people who use post-acute care being slightly more likely to have readmissions than people --

DR. DEAN: More likely?

MR. LISK: Slightly more likely. Slightly more

likely in certain situations.

DR. DEAN: Interesting.

MR. LISK: It will depend upon severity, but it will -- it depends upon severity, but it --

DR. DEAN: It would seem it should be the other way.

MR. HACKBARTH: I assume it's because the use of post-acute care is sort of a marker for the difficulty of the patient.

DR. DEAN: All right.

DR. BAICKER: I thought this was really helpful. Risk adjustment is so important to all the different policies that we're considering, so getting into the meat of this is great.

I wonder how predictable these variations in expenditures in post-acute care versus hospital care versus other kinds of care are. In other words, if you did the best risk adjustment you could, how much of the variation in this can we predict relative to how much of the variation we can predict in other types of settings? And I know the answer to that has to be given with the caveat that what we're observing is already responding to the incentives that

are in the system, so it's not an efficient use. But the success of the risk adjusters will depend on how predictive they are.

DR. CARTER: We've been looking at other people's work that have started to pull in the chronic diseases of patients, and we're pretty optimistic that the adjustment that you can do looking at those is going to be comparable, at least, to what we already have on the inpatient hospital side.

DR. MARK MILLER: Can I add just one thing here? Another thing to keep in mind as you go through this, you'll build risk adjustment systems. They'll explain some degree of the variation. There will still be variation out there. And, remember, you'll have other design features to try to mitigate risk -- outlier policies and that type of thing. So when you think this is the guts of the risk adjustment, then you'll also want to think about other design features as we move forward to mitigate I got a bunch of patients that were real outliers, that type of thing.

DR. BAICKER: And also to match the risk adjusters to how well the providers can predict that when they're choosing or trying to choose their patient pools. That's

the ex ante prediction that I'm worried about, in addition to the protection of risk ex post.

DR. MARK MILLER: So we've also thought about t his. I think this is right. So you can think of risk at two ends, so the provider, you know, through no fault of their own, ended up with a set of patients that were very expensive, and you might want an outlier policy for that. If you think a lot of selection is going on, you might want an inlier policy to protection the program. And we've been talking internally about those kinds of thoughts.

DR. CARTER: And the only thing I wanted to add, of course, is that over time we would expect the variation -- once a bundled payment system was in place, you would expect the variation to decline.

MR. GEORGE MILLER: I've got a quick question on Slide 13. What is your definition of a caregiver as one of the risk-adjusted factors?

DR. CARTER: Somebody at home was what we meant.

MR. GEORGE MILLER: So if my 87-year-old father is present with my 72-year-old mother, that's a caregiver, versus --

DR. CARTER: I understand the point you're making.

We put this up because there had been this consideration in the design of post-acute settings, and I don't know how far down the road they went in thinking about that, but your point is well taken.

MR. GEORGE MILLER: Yes, okay. More important, or equally as important, on Slide 9, just a clarifying question. I remember the slide where you showed the location of some of these PACs, especially the LTCHs and the IRFs. So I realize the costs are the costs, but are some of the costs over time dependent upon if these locations are available? A hospital or a physician may not have a lower-cost facility available, so they may be directed to one of these locations, and it may be geographic distribution. So I wonder if that's affecting the cost, although I realize these empirical numbers are the costs no matter where the setting is. So if there's not an equal distribution of post-acute care settings, will that have an effect?

DR. CARTER: I mean, there has been work looking at the proximity of different providers, different types of providers, and it does influence the selection. But we have not looked at sort of the lack of -- sort of in a marketplace. We have not done that work to see whether a

provider didn't have a lower-cost option. But others have looked at that and have seen that the availability and proximity does influence choice.

MR. GEORGE MILLER: Okay.

MR. HACKBARTH: My recollection of our past work is that if there are LTCHs, for example, available, all other things being equal --

MR. GEORGE MILLER: Being equal, right.

MR. HACKBARTH: -- the post-acute care costs are going to be higher.

MR. GEORGE MILLER: Exactly.

MR. HACKBARTH: But that's in the context of a system where there's no incentive for anybody to avoid a high-cost provider if there's a lower-cost substitute available. So if you change the incentives through bundling, it may be that now somebody has a reason to say, well, maybe we could use a skilled nursing facility as opposed to an LTCH, and the historic patterns would change.

MR. GEORGE MILLER: And this may be my round two -

MR. HACKBARTH: There's a question mark at the end of that, incidentally.

MR. GEORGE MILLER: This may be my round two

comment, but should we consider making that definitional to direct where that patient should go by definition of what's the most appropriate place to go?

MR. HACKBARTH: Yeah [off microphone].

MR. GEORGE MILLER: I'll wait until the next round.

DR. KANE: Two questions. One is when we're talking about the length of the bundle, is there something that -- does it have to be the same for every condition? I would think you'd expect the length to vary by, you know, the type of condition, like coronary artery -- I mean, like, you know, heart failure versus stroke.

MR. LISK: I think if you get down to condition-specific, you may decide that it may be appropriate to have a different length bundle for different types of services.

DR. KANE: But in doing your research, do you want to also sort of see that you're capturing those length differences? I mean, I'm afraid if you're always saying just cut off at 30 days, you might be missing something about strokes that's quite different than something about heart failure. I'm just worried a little bit about the arbitrariness of the 30-day.

Then the other question I had, it seems to me that the MA plans at one point were supposed to be producing encounter data, and I have two questions about that. One, are they, and when is it coming? And, B, are they also going to be providing it on their post-acute utilization? Because I think that would be a useful data set, if it's ever coming.

DR. MARK MILLER: Right, and I may need an assist here from Carlos, but I know on October 25th, CMS is having an open session with the industry about the collection of the encounter --

MR. ZARABOZO: [Off microphone] They are expecting to begin collection in 2012.

DR. KANE: Begin? I thought they started that long-no?

PARTICIPANT: One would have hoped.

DR. KANE: What's so hard about it?

[Inaudible comment, laughter.]

DR. KANE: Wise idea, Carlos.

MR. KUHN: A quick question. Help me recollect kind of what all they can do a little bit, but I'm thinking about the grouper softwares, the episode groupers, the ETGs,

the MEGs, et cetera. Is there any utility in those softwares to help in terms of the risk adjustment in this space in the future that you're aware of right now? Or are they just simply kind of grouping the services together? Or do they have any application on risk adjustment at all?

MS. MUTTI: Those groupers do have an implicit risk adjustment in them, and I think it's the ETGs has a version where you can actually start the episode with the hospitalization. Yes, I think it's the ETGs. So you could apply it using that -- now, I guess there's been some controversy, and there are always issues as to the validity of those groupers, but it's a possibility.

MR. LISK: Can I follow up a little bit in terms of, let's say, the ETGs? What you're doing is you're going to be getting all services that are related to the condition the person had versus some other type of method, some other types of things, HCCs or CRGs, that may be out there which would risk-adjust for all services type of thing. So you kind of have that choice of are you going to choose what are related or are you going to try to get everything in?

DR. CASTELLANOS: It's really a follow-up on a little comment that Mark made, and maybe George. One of the

real-world problems that we have is bed availability, when the person is -- as you can see, there's a tremendous variation, but when a person, say, needs to go to a post-acute care setting, that facility has the right to come in, look at the chart, and decide yes or no. I'm not saying that's stinting, but it's stinting.

[Laughter.]

DR. CASTELLANOS: But, you know, will the -- I guess my question is: Will the bundling help making these decisions and prevent the appropriate facility saying no because it's going to cost too much or it's going to be a high-cost patient?

DR. MARK MILLER: I think what I would say is that anytime you have a bundled or prospective payment -- which, just for starters, we have that now, except that right now it's fragmented across different providers, at least in the post-acute care setting that we're talking about -- you run the risk of stinting. So the risk will be there that someone will look at the payment and try to avoid patients. You bring this up always, Jennie, and that risk is always present. And I think the question for us is: A, how much can you remove that from a risk adjustment system, whether

it's based on functional status, diagnosis, whatever we end up thinking helps? And, two, whether you can mitigate that risk through other design -- outliers, that type of thing.

But I believe, you know, the basic incentive is always present, and you can also overlay outcomes and make part of their payment contingent on did the person get discharged to the community, did the person get readmitted, and try and mitigate that. But I think the incentive structure --

DR. BERENSON: Except I would add that at least in theory the recipient of the bundle has much more leverage over the behavior of the other parties. And so it might be much more difficult. For better or for worse, the recipient of the bundle can probably have leverage to tell that particular facility that if you want the other patients, you're going to take this patient. I suppose that's what some people want to have happen. I'm a little nervous about that myself.

MS. UCCELLO: I just want to confirm. Is one of the questions of this whether to construct the bundles just for those who get post-acute care versus broadly over the entire episode, including the hospitalization part?

DR. CARTER: We think it is a design issue because if you pay all bundles the same rate, you will be overpaying for patients who don't receive post-acute care and probably underpaying for those who do. On the other hand, you've now created an incentive for everyone to get PAC, so we think that -

MS. UCCELLO: Right, yes. So my follow-up to that is, if there is -- if it's just for those who receive the post-acute care, those inlier adjustments are more important. So I just want to get a better sense of what exactly that is or if it's just if the spending is less than a certain amount then they don't get -- I want more information on what that would be.

DR. CARTER: I actually don't understand. What's the "that"? I've lost your question.

MR. HACKBARTH: Cori's point is that if you can increase your payment by having some post-acute care, there's an incentive to refer a patient to post-acute care for just a little. And when that incentive exists, you need the inlier policies to try to diminish that potential.

DR. MARK MILLER: And so, going forward, we're going to have to think about how to do that. Some of the

existing inlier policies that, you know, exist in Medicare can be triggered by things like how many visits did they get in the home health -- right. So in the home health setting, it sort of implicitly assumes a set of visits, but if you don't hit -- and I don't remember the number -- three, four, five, whatever visits, then you don't get the full episode payment. It would be mechanisms like that, but I don't think we could answer exactly on the spot.

MS. UCCELLO: That's exactly what I -- I didn't mean to make this a round two question, but, yes, was it number of visits or dollars or something like that, and it could depend.

MR. HACKBARTH: Round one questions?

MR. BUTLER: So I love this data. Finally, we're looking across our silos in a quantifiable, measurable way, regardless of how hard it is to put the system in place.

As small as the number may be, did you consider hospice? Because this isn't the population that typically uses it, but you'd think that would be one of the columns.

MR. LISK: Unfortunately, because of the way the data was originally created, people who used hospice were taken out of the analysis file. And so we did remove all

people who died within the episode window for this analysis and also people who didn't have hospice. But, you're right, I think hospice would be one thing to potentially consider here --

MR. BUTLER: Especially if you move to other --

MR. LISK: -- but what we had, we couldn't do that.

MR. BUTLER: -- episodes, I think that would be a very interesting addition.

Second, not related to severity but I still want to ask it, 45 years ago Congress decided thou shalt not bundle when they started Medicare with physicians and all the rest, and we've been trying to bundle ever since. So on the pilots that you mention that include -- you know, that physician payments as well as post-acute care are in some of those bundled pilots, can you tell me are those payments going to systems that own all of the components, or have they, in fact, figured out how to accept the bundle and then distribute it to whether it's private physicians or non-owned post-acute providers? Have the logistics been worked out for that?

DR. CARTER: Are you talking about the pilots that

CMS is going to be setting up?

MR. BUTLER: Not just CMS. You have IHI. You have others in the document that have used bundled payments.

DR. CARTER: Right.

MR. BUTLER: I know in just the inpatient bundling between physician and hospital payments, those have been worked out. But, you know, the full-blown post-acute care physician where you don't own all the components, the recipient of the bundle, can we cite an example where that thing has been worked out logistically?

DR. CARTER: My general sense is typically those exclude institutional post-acute care. They might include PT and outpatient rehab, but they have not included post-acute care. But I'll get back to you about that because I'm not sure. I've read the contracting documents, but I couldn't tell from reading them whether it was contracting with one of their system providers or not. So I don't know.

MS. MUTTI: And your question may still be relevant even if it's not post-acute care, even if it's just hospitals and physicians. But, you know, how do they divide up the money? We've talked to IHI a little bit, but we need to talk to them a little bit more to answer that question,

probably. That's the Integrated Healthcare Institute in California. So we can get a better answer for you on that. Minnesota I don't think is as far along as California is, so we might not have an answer yet on them. But we'll get back to you on that.

MS. HANSEN: I just wanted to say thank you. I think this chapter and the body of work is just a real important piece.

I'd like to go to Slide 10 just to ask a question. I think I heard you say, Carol, that the second bullet, which is adjust for chronic conditions, does not consider some of the issues like mental illness. Is that right?

DR. CARTER: No. What I was saying was that the hospital coding may not, and that one of the things we need to do is to expand the use of diagnosis information from the post-acute care providers because we think it will do a better job of collecting the chronic conditions and comorbidities of the patients.

MS. HANSEN: Great. Well, it relates then also to people -- actually, this is a question. Is there a coding process to capture people who have Alzheimer's disease or dementia as a part of that as well? And the reason I ask

about both mental illness and that kind of chronicity of cognition is that that factor, those two conditions become a multiplier from my experience. So making sure that there is sufficient adjustment for that multiplier effect is important to capture in order to have a fair risk adjustment per se.

DR. CARTER: I think that raises a couple of possibilities that we can look into. One is looking at the -- I think at least two of the post-acute care settings and the patient assessment tool, there is some measure of cognitive function. And we might be able to sort out and then just use a sort of a flag whether that patient has dementia. I don't know -- we haven't looked at sort of the completeness of coding for dementia patients and post-acute coding, but we can do that to see whether it's better. Some of these patients presumably have some risk scores from, you know, the HCC. We haven't looked at that, but that's a possibility as well to see whether that coding is a little more complete.

MR. HACKBARTH: Round two comments? And we have, let's see, a little over a half-hour to go.

DR. BORMAN: I'm glad that we're still on this

slide, because I think bullet number three there is hugely important, as I know you folks understand enormously well, having dug into this in this very elegant way. And I think probably -- and part of the problem is that everybody that has something to do with health care has been trained in some fashion to take patient problems apart in order to deal with them in a meaningful way, and I think we have a great ability to pick things apart and to think of all the things we'd like to have in there, and yet at the end of the day, there's no system that can get to somewhere that the R-squared correlation is perfect and we're there.

So I think we have to say, what is a target level that may be, in fact, good enough to proceed. I certainly don't have that answer and you folks will do a much better job of that.

I would throw out that I think one of the lessons, at least, of risk prediction from clinical studies, at least in the world of surgery, is that it's amazing we can devise these very elegant things that can be very disease or operation-specific and have lots of data elements, but a lot of times they track with some things that are very simple measures, and you may lose a little bit of precision but

they track, and that's kind of, I would think, the thing we're looking for, is a relatively limited data set that tracks a fair amount of it.

And so, for example, as you're looking here, you've got a couple of things that surround surgical hospitalizations, if you will. The ASA class, the American Society of Anesthesiologists stratification system, is a pretty straightforward one, just got one set of levels with or without an emergency designator, and it's amazing how predictive that is sometimes in outcomes.

And Tom may be able to speak to it better, but there's also, for example, on the oncology side, and certainly we have a fair amount of malignancy burden in the population we're dealing with, the performance score of many trial programs, there's a couple of very standardized ways to estimate the status of that patient. You can parse out the ones that relate to their cancer, so there's sort of some left that evaluate the general status of this patient to tolerate therapy. And so those -- I think one of them is the Karnofsky performance score. Something like that might be something to just look at those as examples of things that might be useful, might not, but come to mind in this.

DR. STUART: I have a couple of observations, but a technical question first. In this chapter, you speak about picking a hospital admission and then going out to 30 days, and in other cases 60 days or 90 days, and this is over a three-year period?

MR. LISK: -- what we're using is over three years.

DR. STUART: I guess my question is this. Are you picking every hospitalization, or is this kind of an episode of care? In other words, some hospitalizations could be rehospitalizations of a previous hospitalization. Obviously, as your period, duration of the episode gets longer, then that becomes a bigger issue. So just in terms of interpreting your data, what about a hospitalization that might be a rehospitalization?

MR. LISK: Yes. In terms of what we did, is the rehospitalization was not included -- was not a starter of an episode.

DR. STUART: So there was a window --

MR. LISK: Yes.

DR. STUART: -- an exclusion window?

MR. LISK: Yes.

DR. STUART: Okay. It might be useful just to make that clear. Or maybe it was here and I just didn't see it.

I'd like to follow up on a couple of points, one that George had about home caregiver availability. I can certainly understand why you don't have that in there, but it strikes me that there's a real catch-22 here, because there may be a problem having it in there, but it strikes me that there's also a problem not having it in there. The argument would be, well, if you make the payments based upon the assumption that you're blind to that, the institution obviously isn't going to be blind to that and the organization and the physician is not going to be blind to that. And so if under previous circumstances the individual would have ended up under a SNF, but under a bundle there would be more attempts to push that person on an available caregiver.

So I think that warrants evaluation, and it strikes me that this is something you could probably do in the MCBS. They don't tell you the age of the spouse or the caregiver, but I believe they have something about the relationship so that you could find daughters and sons and

things like that. So it might just be worth a look.

The second observation gets to socio-economic status, and you kind of lumped this with duals, and I think duals are special for a couple of reasons, particularly in this context in that you're going to find a lot of them that are in long-term care. Now, we don't call the non-SNF Part A covered long-term care residents post-acute care, but obviously if you've got a significant number of people that are in nursing homes, and we've talked in other contexts of the incentives in some cases to rehospitalize so that you can get a post-acute Part A stay, and so it seems to me that that would be important in the context of this process of trying to understand the incentives.

And then finally, a point that Peter raised, also Glenn raised it, which is I recognize this coming later in your work, which is kind of focused on who gets the payment and how does that influence the structure of the system, and that would be just looking at swing beds and the extent to which hospitals that have swing beds, how that influences the utilization of post-acute care, both not necessarily just in the swing bed, but also other types of post-acute care.

DR. DEAN: I would just follow up with what I said earlier. It would seem that somehow we need to build in the readmission data, because presumably, I mean, we believe we've got a lot of unnecessary readmissions, and presumably if post-acute care is done appropriately, that should be one of the factors that would help reduce that.

And, for instance, I think we could be misled, for instance, if someone went, used the lower-cost post-acute care in one of the institutions you list here, but, in fact, ended up with a higher risk of readmission, we've been misled by the data. I mean, to me, it's a significant factor that somehow needs to be merged in there. I'm not exactly sure how, but --

DR. BAICKER: Apologies for being a little fixated on risk adjustment, but so many of the problems that have come up with inlier payments and outlier payments would be mitigated by having a really good measure of patient severity. And you mentioned HCCs, and I know there are issues with those in terms of variability of coding practices. I have run across that in the geographic variations, where places that treat patients more intensively also code them more intensively, and so the HCCs

are a bit of the mix of the actual severity of the patient and the local practice style and you'd like to just isolate the severity of the patient.

And something that came up yesterday was getting data for some of the -- you know, when we're trying something new or when more money is going out the door, can the price be to get more data back from providers, and is there data that you think would be particularly useful in constructing good measures of patient severity that we don't have, whether it's the lab values when you actually pay for a lab or something that would help us get a much cleaner measure of patient health that could then be an input into lots of these different payments.

DR. CARTER: Actually, when Tom was talking, I was starting to think about going back to the care tool, which I know that data's not going to be here tomorrow, but there are some things about caregiver at home and cognitive and functional status that certainly down the road are going to be available. But I don't think -- I have to look and see what it has on the ancillary service side, but I was thinking about that.

MR. GEORGE MILLER: Yes. I think Bruce very well

covered my comments on the definition of a caregiver. But I want to go back to Slide 9, please, and look at this distribution. I think it was a fair question about why hospice is not there by Peter, but I'm comfortable with the answer.

What I am concerned about on this slide is the outcomes. Do you have -- if a patient, and Tom mentioned about readmission, do we have better outcomes with the same level of service if someone goes to a SNF versus an LTCH or vice-versa, and how does that drive the decision going forward, particularly back to my original statement, if one of these post-acute services is not available, or if they are available, does a physician have a choice, or do they start out at the low end and then go back and they go back into the hospital, then readmit. How do we account for all that variation? That's more of a statement-question than a question-question.

DR. CARTER: One thing we could do is look at the spending patterns by readmission rates, or -- you know, at this point, we're stuck with outcomes that use administrative data, so we're going to be looking at -- and this data at least excludes deaths, and so at least

mortality rates, you wouldn't use these data for that. But we could look at what do spending patterns look like, controlling for readmission rates.

MR. GEORGE MILLER: And then finally, and I apologize because I said this earlier, would the Commission want to venture into then defining what we think may be the more appropriate place to go, or is that something we should leave into the hands of the physician, especially if you're talking about trying to lower cost in the market. So if you have a choice between spending $569 or $22,000, should we define that?

MR. HACKBARTH: A hard thing to do in the abstract, is the challenge. It depends on the specifics of the patient, what is the best setting for them.

MR. GEORGE MILLER: That's why I asked the question about the outcomes. Do we get better outcomes --

MR. HACKBARTH: Well, we have our chronic problem in the post-acute area. We've been doing analysis of outcomes for the patients in different types of settings because we find it difficult to -- we don't have common assessment instruments and the like and so it's very difficult to make comparisons.

But part of the thinking here is that if you can create an appropriate incentive, people who are much closer to the patient and the circumstances will now have a reason to seek out the most efficient provider of the needed services. And so as opposed to trying to do it through long distance, an insurer with classification systems, people on the ground who know what the capabilities of the SNFs are versus the long-term care hospitals can make those judgments.

Now, you need to worry, as we always do in these situations, of whether the incentive to stint on care will be so powerful, and so you need measures of outcomes that you're reasonably confident in.

But a large part of what we'd be trying to accomplish here is move the locus of decision making to people who have the information and give them an incentive to do the efficient thing, the low-cost, high-quality option.

MR. GEORGE MILLER: [Off microphone.]

MR. HACKBARTH: That's right.

MR. LISK: Can I just -- I'm sorry. On this slide, I just want to make one point, though, too, when

you're talking about the variation. We're just looking at 30-day spending and it cuts off, so people continue to use spending. So we don't know, let's say, what the spending is for 180 days, for instance, for some of these people in terms of the outcomes, so --

MR. ARMSTRONG: Actually, I think the comment that I'd like to -- or the observation that I'd like to make fits somewhere in the neighborhood of this conversation. I'm afraid I don't have a lot to contribute to some of the methodology around risk adjustment, but I would just say, in my experience working in the system that I work in, we spend a lot of time focusing on more efficiently using post-acute care services by thinking about how the acute care experience for a patient unfolds. And we know that if a patient is discharged with explicit instructions around their pharmaceuticals, we know that if a patient is discharged expecting a follow-up call within 48 calls regardless of where they are from the nurse that saw them in the hospital, or we know that if a patient will expect to be contacted either in person or in some other way by their primary care provider within the first few days after being discharged -- again, regardless of where they end up being

admitted -- that that lowers readmission rates and it lowers overall costs.

And so I don't know how this contributes to this methodology or this analysis, but it seems to me that some consideration of how care evolves up to the discharge and is kind of coordinated, if you will, through these various alternative settings, post-acute care, might also be worth considering as part of a way of encouraging or evaluating the different costs of these different paths.

DR. KANE: Yes. Actually, I was thinking about the pharmaceutical piece, as well, noticing, of course, as usual, Part D is not in here, but --

DR. MARK MILLER: [Off microphone.] It was in yesterday.

DR. KANE: It was in -- I'm glad to hear that. I saw that, but, of course, it wasn't linked at the individual level. I'm hoping that's not because you can't link it at the individual level, but I liked it. I liked it. I really did. I liked --

DR. MARK MILLER: It will be in the next section.

DR. KANE: It's going to be in the next section. I read about it.

But one thing I was thinking, if you're having trouble identifying people with mental illness or something, it might well be in the Part D data set that they're taking certain drugs and that could help you identify the people who have -- if you can combine those two. I'm still not -- I've got a feeling you can't, but if you can.

But then the other thought I had, and I was thinking about what Cori said about the incentives to start putting more people into these bundles if you can get a higher payment, can we somehow integrate that with the ACO identification methodology and create populations of patients and look at rates of utilization of post-acute by condition and try to come up with some sense of what the most efficient ACO type systems do, you know, what rate is kind of reasonable? I don't know. I mean, I know it's hard to get to the outcome, but if you can start to do a population base rather than a --

MR. HACKBARTH: Yes.

DR. KANE: -- individual patient base and see rates of post-acute --

MR. HACKBARTH: So you're saying to create a market-specific benchmark --

DR. KANE: Yes.

MR. HACKBARTH: -- against which you can compare -

DR. KANE: Whether they're over --

MR. HACKBARTH: Yes.

DR. KANE: -- you know, whether the post-acute usage -- until we get this other thing in this demo to work for us, that there might be --

MR. HACKBARTH: Although one challenge in doing that, I guess, would be shifts in market share, to the extent that the increase in the admissions is because they've succeeded in attracting more patients.

DR. KANE: Well, you would do this at the condition -- in other words, so you would say, for this ACO versus that ACO in Chicago, all people with strokes, you would try to get a sense of the stroke by severity level. The most efficient place where they don't end up with disasters at the end uses this pattern of care going through the post-acute, whereas the less efficient uses that, and you get some sense of what the right amount of -- we're just going cold here. We don't know what the right pattern is yet. And until we get this post-acute demo stuff to start working, I'm just thinking, go to the population level and

the ACO level. Just try to integrate that to come up with what's the most efficient care pathway that we can see within a market, and that adjusts for what's available in the market, I think. I'm just trying to think of how do you get at what's the right amount of the different types of providers, conditioned probably by severity. Anyway, it's just the thinking of trying to integrate some of the other types of analyses that are going on and seeing if you can draw --

And I guess my last comment is I really do think you need to think something about the socio-economic status. Now, maybe a dual eligible is the best way to do that, but they are well known for being the most difficult to manage for a variety of reasons, so I don't think you can ignore that very easily.

MR. KUHN: One of the reasons that when CMS took up the effort to put together the standardized patient assessment instrument was that, you know, hopefully, the long-term vision was to create a site-neutral payment system in the post-acute care setting and a way to get rid of kind of what you see up on that chart right there. That is, create the incentive for providers not to choose the post-

acute care setting that generated the highest payment, but which one was the right selection spot for that patient based on their needs and their assessment that are out there.

So as I think about this tool, and as in the paper, you know, next year, hopefully, it will be closer to finalized, and I think that will be an important tool as we move forward with this whole bundling concept, are there other Commission recommendations that have been made in the past to refine any of the post-acute care payment settings that haven't been acted on, but if those refinements were in place would create a better platform or better opportunity for us to mange the bundling on a go-forward basis? So what I'm thinking about is that is there still some developmental work in the post-acute care effort in those fee-for-service areas that would create either -- make it easier or create -- make it a better opportunity to develop the bundling, and if so, do we want to bring those back up and make that as part of this overall discussion, as well?

DR. CARTER: Well, a couple of things come to mind, but I'm not sure if this is what you're thinking about. We have made recommendations before about the

payment system for Skilled Nursing Facilities and have looked at the home health payment system because of the way service provision and the specific service use is incorporated into the payment systems. That really drives service use and spending.

And so those are recommendations that we could come back to, because as one of the slides points out, current spending levels aren't probably where they need to be in terms of taking care of patients and it's a reflection of the payment system.

MR. KUHN: Yes, that is exactly kind of what I was thinking, because if we are trying to build a bundle on some flawed systems out there and we have recommendations to refine those systems, I think we need to keep revisiting those in order to make sure that the foundational work is as good as it can be.

DR. CARTER: And even a different one of, say, having patient and facility criteria for long-term care hospitals. I mean, right now, the only thing differentiating those are the 25-day length of stay, which is -- and that's a recommendation that we have made before.

DR. MARK MILLER: When we get to December, you'll

see packages on -- because in December, we're back into working with silos, whether you want to or not, back into working with silos and so you'll have the update recommendations and packages of things where we'll go back to revisit the things that have not been implemented and put them back in front of you and either just roll them along into the March report or ask you to reconsider them, that type of thing. So you will get this opportunity.

DR. BERENSON: Yes. I'm sort of where Bruce was in round one, which is that this is water that I'm not sure I want to put my toes too far into, but I'm convinced that we're going to learn an awful lot by this, whether or not we actually have a successful demonstration of bundled payments. So I actually think we want to give a lot of attention to the silos, partly to help us in the bundles, but partly because we may be dealing with silos for quite a while and we could try to address some of the perverse incentives within those silos. But this is heroic work and good luck.

The one specific thing I wanted --

[Laughter.]

DR. BERENSON: The one specific suggestion -- I

actually think the sort of family situation, the community supports has to be an important area that goes into the decision around where to discharge, and whatever we can sort of bring up on that, the discussion that George and Bruce had, I think is an important one and I think we need to understand that as part of a potential part of a risk adjustor.

MR. HACKBARTH: The sad thing, I guess, is I can't think of anything that we deal with that isn't full of problems. Think of our conversations yesterday. If you're going to try to do something that is significantly different, it's complicated. Every single thing we touch is really complicated.

MS. BEHROOZI: On the issue of socio-economic status and presence of a caregiver, I think there's a lot of evidence that shows there's a pretty high degree of correlation, right, and it's not just about a caregiver but a caregiver who is really able to take care of the person, as George raises.

And I wonder -- just throwing this out there, it might be a really dumb idea -- whether -- and it's a little bit related to what Nancy said about looking at populations

-- whether you can do something like look at ZIP codes and income levels within a ZIP code as a way of identifying people who ought to be eligible for a little bit of risk adjustment when they are -- when the bundle is paid on them, rather than the individual.

You know, it's not about their income so much as -- or whether they have a caregiver there and how old that caregiver is, but the neighborhood in which they live, other things that correlate to living in a poor neighborhood. And it's not just about dual eligibles. I think that's far too narrow a definition of poor and doesn't correlate as highly to whether there's a caregiver or not as poverty level generally in a neighborhood. There are other things like the presence of supermarkets or places where you can buy fresh food, opportunities for safe places to exercise when you're recovering from your hip replacement, or things like that, literacy rates, specifically in terms of health literacy.

So if it's possible to look at a more population-based geographic, like ZIP code maybe, kind of definition of low socio-economic status and then that person has a slightly higher reimbursement rate on their bundle attached

to them, not just -- it's obviously because there is a risk that they're going to cost more, but also then the provider has maybe some more resources to do some of the things that Scott talked about in terms of substituting for the fact that people may have low literacy rates and not have caregivers available at home and things like that.

MR. BUTLER: Okay. I will try to be concise, but I have a smorgasbord kind of comments.

The first is the variation question, which is on a lot of our minds. Again, I would remind us that variation in spending is not the issue. It's the variation in the diagnosis and the -- you know, the variation in spending is actually what we're trying to get at. So people try to focus on explaining that and adjusting the payment system, and you're looking at the wrong place. Yet there is a very great concern about variation within episodes and the types of patients. I understand that.

Specifically on what you might look at additionally, I know in our own organization and historically, ventilator treatment as an individual thing is a huge, huge resource consumer and something that we never have quite come to grips with, and I imagine it's a big

predictor of LTCHs and all the rest. So if you look at that as a specific variable, I think it might explain some things. Kind of associated with that is tracheostomy, which, you know, we created this humongous DRG to recognize that. So those two things as variables, you might look at.

Now, it's fascinating to see the audience is about half today as what it was for ACOs, which tells you where the energy is going in terms of people are assembling ACOs, and for some very good reasons, but mostly it's around keeping their patients and market share. The genuine interest in managing the population, yet very little attention right now is going on in organizations on this data and this is where the rubber meets the road. This is where change is occurring, at the episode level, not in aggregating components of the system. So we have to think about how we really engage people in this activity.

It gets back to Scott's point yesterday. If you have the metrics or something up here, this is a level I can engage physicians on, whether you use it for payment or not. We -- and also, those who participate in capitation know just accepting capitation does not necessarily -- you know, we created capitated systems and then handed out the money

on a fee-for-service basis to doctors. It doesn't change and engage the physicians differently.

So why am I excited about this? So let's take stroke. It's a major illness, and we sit there and we have -- the Joint Commission now have stroke center certification, right. Big deal. People will go after that. But it's primarily around their ability to handle the acute part of strokes, to provide treatment on a timely basis so we meticulously understand the processes within the acute state. Why wouldn't you kind of extend that concept across these silos? It makes perfect sense and would force the coordination. And why wouldn't you want to look at hospital-specific -- let's take all the Chicago hospitals and lay this profile out on this slide for stroke and where it's going now, and why couldn't you extend kind of the readmission rate kind of concept in some way to these other components of care?

Now I'm getting beyond the logistics, but you could almost do accountable care organization by disease, in a way, in a sense, without accepting the bundle, distributing the payments, but incentivizing somehow across these silos appropriate performance, and for those that

think it's hospital-centric, you could even bundle just the post-acute part as a package, potentially, and now I'm really brainstorming, but I think if you really want to improve the health -- and by the way, the quality and outcome measures, they line up with -- if you want to say, well, what should we collect on quality, it would be very easy to do for something like stroke. It gets focused on the diseases we're trying to address in a meaningful way across a population.

So there's a part of me that says there is a real potential here and it's the right place to focus improvement and reduce variation in the system. So this is my pitch for -- a year ago, I would have said, let's go to the ACO level. I'm now thinking more like more change is going to occur with a focus and understanding at this level than at an ACO level.

MR. HACKBARTH: That's what I was just going to ask. It seems to me that there's a different emphasis this time than in some previous conversations, so I heard it correctly.

MR. BUTLER: And I might change my mind, on another one, the logistics --

[Laughter.]

MR. BUTLER: I think fully capitated programs are still a very good way to go, as well, but if you really want us to create change, getting at this data ultimately at this level is going to be where the most change occurs, I think.

DR. MARK MILLER: [Off microphone.] Can I say just one thing? I mean, the reason I want to come at this point is sort of about what the Commission does and why we may have different oars in the water, or whatever the analogy is at the same time, because you don't know which way these are going to go necessarily and you don't know that it's going to go in all areas.

So in ACOs, may form in some areas, but you may still want this work, A, because there may not be ACOs everywhere, or they may actually complement in some way what is going on underneath ACOs. So I just wanted to kind of make that point. It's not always about picking a horse. It's maybe running a lot of them to see which ones --

MS. HANSEN: Yes. Well, it's interesting. This is unusual for me, because I'm also taking -- usually, as you know, I'm much more patient or beneficiary-centric. In this case, one of the questions that was brought up by

George and then I think brought up by Nancy is thinking about the use of the resources, and I am so struck by this because there was, a couple years ago when we looked at IRFs and LTCHs, being visual as I am I asked, gee, where are these located, and so we had a geographic map and the spread and you saw the clustering.

And what was interesting is, and I think Bend, Oregon, was one of the areas that had few, if any, resources in this area, so there is actually a population-based way to think about how do people with conditions manage when there are rather pure areas that don't have some of these resources at all and yet everybody more or less, I think, as I recall, has access to home health care, and that's kind of a -- there is a distribution that all counties are covered -- except certain rural areas. But on the aggregate, there are far more availabilities.

For people who have these conditions, whether it's cardiac conditions or strokes, I mean, they go home somewhere, and so there is a natural way to kind of almost wonder for these States and big regions that have zero and yet somehow the patients have the same conditions that they're afflicted with and go home, you know, what's the

difference and what's the readmission rate, all the things that we're looking at, because that's a population approach to it as compared to thinking about it individually.

DR. CHERNEW: So I'm going to both agree and disagree with Peter as we go through this. I actually think this illustrates why there's a problem with episode-based bundling as opposed to a broader capitation-based bundling, because the incentives you have at the seams in all kinds of ways and the gaming becomes atrocious in ways that I'll say in a minute.

I agree with Peter that the actual action has to occur lower in this clinical way, the way Peter would think about it, the way Scott would think about it, but I'm not sure that the Medicare program has to try and figure out how to get the incentives right down there as opposed to have a higher level of incentive and if one of those organizations, an ACO or whatever, wants to pay everybody fee-for-service, that's not going to be very successful.

So they're going to have to find a better way in their setting of working out these complicated bundling systems, and it's going to matter based on how much they can monitor or not or what the resources available are or not,

and the problem that I think we face when we try and get this episode-based payment right is we have all of these problems that different parts of the country are different, different settings are different with different resources, and we have a really hard time getting an episode bundling right when we don't know when the right end of the episode should be, and so that creates a problem, for example, and we're going to have to rebase the other post-acute services thing, because now part of that would be in the episode and another part wouldn't.

We have the inlier problem that we're going to have to figure out how to deal with, and that creates all kinds of incentives around whatever threshold you put on the inlier, and outliers creates all kinds of incentives on the outlier problem.

And then there's all kinds of coding problems about which of these things we want to code or not code.

So I'm very supportive of certain things, like Mitra's point about the ZIP code matters, because although you won't get it right at the individual person level, you want to make sure that institutions that serve people that are coming from certain areas get more, and I think the ZIP

code stuff will do a really good job of getting that right, although there will still be variation across the individuals.

So overall, my preference is we have to do this for the reasons that Mark said. I agree completely, they might do this. I would be happy if we emphasized in part of the text the fact that there are some inherent gaming problems with episode-based bundling, and some transcend. As people have multiple episodes, what do you do? What happens if someone is in a middle of a stay somewhere and then they have a stroke, and now they're -- just dealing with all of these scenes are incredibly complicated when you have to right the regulations and it scares me more than it might have before.

So while we have to do this, admittedly, I personally would like some circumspection about how hard it is and why one might want to go to a higher level and let the lower levels work this out in how they deal with it, even though I completely agree that all the action will only be successful if the lower levels of the system do a good job.

MR. HACKBARTH: You know, global capitation is

clearly a more elegant solution --

DR. CHERNEW: With quality measures.

MR. HACKBARTH: With quality measures.

DR. CHERNEW: With quality measures and other safeguards.

MR. HACKBARTH: Yes, and --

[Laughter.]

DR. CHERNEW: Adjustment.

MR. HACKBARTH: Right.

DR. MARK MILLER: It's starting to sound complicated.

MR. HACKBARTH: Yes. I really believe that. That's the world that I come from. Having said that, the other piece of this is how difficult it is to form and run those organizations and bring these disparate types of providers and institutions and make them into functioning organizations.

So yes, look just from a policy perspective, an incentive perspective, global capitation is very attractive. But on the ground, trying to forge from this chaotic delivery system these coherent, well-functioning organizations is a huge problem of a different sort, and so

I think some places will be more ready to do that than others. And so I'm with Mark on the horses. Let's keep lots of different horses going.

DR. NAYLOR: So our team has been working in this for about 25 years, looking at how it is that you can take high-risk individuals at their index hospitalization, and maybe not from the time they are coming in from the ambulance, but from the time they arrive in the hospital to do a much better job at improving care coordination, preventing seeds of readmission being planted in hospitals, following them for periods of time post-discharge, to prevent long-term. So we followed and reduced hospital readmissions through 12 months, et cetera, and we have learned a great deal along the way.

So I want to first congratulate you, because I think that it may be part of a bigger system change called ACOs, but we know that this is a really important opportunity and bundled payment represents a mechanism that aligns payment with the care needs of people over episodes of care. So we've demonstrated this, multiple clinical trials. We've replicated it in real world organizations, achieving the same kind of clinical and economic outcomes.

And here's a couple of things that I would say to you.

It may not be a part of what we start with today, but I do think we need to have common measures of risk assessment that start at acute episode that could also be used for payment. So whether it's the continuity of care record, but we need to make sure that we have measures, because the measures available to us in the administrative database are not going to be at all effective in helping us get there. We may need to be thinking about clusters of measures.

So we've seen consistently in randomized clinical trials the number of chronic conditions associated with active therapies when added with functional status give you a better sense of who's at risk. We know that cognitive impairment is not identified, so having -- very few have a diagnosis of dementia, and in our clinical trials, 35 percent of people coming into emergency rooms have some form of cognitive impairment and 65 percent of them are not identified, and yet that's a risk factor.

So I know that we have some beginning sense of what are individual factors, what might be weighted, what might be clusters of factors that could help. But it really

does -- I don't think you can wait until the post-acute care environment to achieve the goals of bundled payment, which are really to achieve better care, efficient care. So I would say that.

I would also say that we've really been into the post-acute environment data and the data are not there to help you get at really good risk assessment, at least right now. So we need to have more than that.

And I also think that the real opportunity here is, of course, to risk adjust for payment, but it has to be linked with performance. I mean, people have said this 1,000 times. Really, the ultimate game here is to make sure that we do better care and we demonstrate better care. So not having it linked to performance in both quality measures, function, or readmissions and reductions in cost over the long haul, I think is -- I know that that's ultimately the game and you're going to give payment. Your payment, though, should not be just to risk adjust, but it should be linked to the performance.

So I could go on, but I think this is a really important area to focus on and I think your work has really positioned us to make real gains in this, so thanks.

MR. HACKBARTH: Okay. Thank you. Good work. We look forward to hearing more about it.

And our last session is on regional variation in service use.

[Pause]

DR. ZABINSKI: Before we start, we'd just like to publicly thank Jeff Stensland and David Glass for their input on this work.

Many states indicate large regional differences in the service use among Medicare beneficiaries and this regional variation can indicate differences in both the volume and the intensity of the services that are provided. Because of the variation, some have argued that aggregate's health care spending can be substantially reduced if the high use areas are brought down to the levels of the low use areas.

In previous work on this issue, we sought to add clarity to the literature by drawing distinctions between the variation in spending and the variation in service use. Today, Shinobu and I will talk about two ways we have extended our previous work on this issue. First, we will use a new data source and a new source of adjusting the

Medicare spending reported on that data to obtain measures of service use. Second, we augment our analysis of service use by adding prescription drug use. For that part of the analysis, we measure the variation in drug use alone and variation in service use and drug use combined.

First we'll just discuss our work on service use alone. The data sources we used in this study, as well as in our previous work, give us spending and fee-for-service Medicare. However, we are interested in variation in service use, not variation in raw spending.

Therefore, we always adjust our spending for regional differences in several factors including input prices such as hospital weighted indexes, special payments to providers including IME, DSH, additional payments to some rural hospitals, and HPSA and PSA bonuses that go to some physicians. We also adjust for demographics such as age and sex and beneficiary's health status.

The result of these adjustments to the spending is a measure of service use that reflects regional differences in providers' practice patterns and patients' care decisions. We are interested in this measure of service use because it lets you separate areas where the practice of

medicine is relatively resource intensive from areas where it is less so. This allows policy makers to focus on factors that can help control program spending.

The importance of making those adjustments to spending is reflected in previous work we presented at the September 2009 public meeting and published in the December 2009 report. In this diagram, it's from that study except for the data that is more recent than what we used in that study. Here we used data from 2005 through 2007. This diagram indicates that variation in service use is much smaller than the variation in spending.

For example, we estimate that about 45 percent of beneficiaries live in regions where per capita service use is within 5 percent of the national average, but only about 25 percent of beneficiaries live in regions where per capita spending is within 5 percent of the national average. It's the two center slides above 95-105.

The data we used in this study from December 2009 are from the Office of the Actuary at CMS, OACT, and include county level program spending for all beneficiaries in fee-for-service Medicare. Under this old method, we have pinged service use from the OACT data using arithmetic methods to

adjust OACT spending for regional differences in prices, special payments to providers, demographics, and health status.

Today we revisit this analysis with a new method that employs beneficiary level spending in fee-for-service Medicare from the Beneficiary Annual Summary File, or BASF. These data cover 2006 through 2008 and also include program spending for all fee-for-service beneficiaries. To obtain regional service use from that file, we used a regression model to adjust the spending for regional differences in prices, special payments to providers, demographics, and health status.

We're not going to get into all of the details about our methods, but we do want to cover a few key points. First, to define regions, we combined urban counties into metropolitan statistical areas, or MSAs, and all other counties into non-metropolitan rest-of-state areas. This produced 409 regions.

Second, in our older method, we adjust for regional differences in health status using county average risk scores for fee-for-service beneficiaries from the CMS-HCC model that are provided with the OACT data for the CMS-

HCC is the model that CMS uses to risk adjust the capitated payments in the Medicare Advantage Program.

Third, in the new method, we use a regression model that includes the following adjusters: Demographics such as age and sex, all the health factors that are in the CMS-HCC model, and indicators for each region.

On this diagram, we show the distribution across regions of the service use we estimate from both the BASF and the OACT data files. The diagram indicates that the two data sources produce very similar distributions. For example, we estimate that both data sources have about 45 percent of beneficiaries living in regions where per capita service use is within 5 percent of the national average. Once again, that's the two center bars.

In addition, the correlation coefficient between the regional service use from the two data sources is about .95.

Another way to view variation from the two data sources is to examine extreme values. For example, from both data sources, we compared service use for the regions at the 90th percentile to service use for the region at the 10th percentile. Once again, the results are very similar

for the two data sources. In the OACT file, service use at the 90th percentile is about 29 percent greater compared to the region at the 10th percentile. In the BASF, the region at the 90th percentile is about 30 percent greater than the region at the 10th percentile.

So a natural question is, if you're getting nearly identical results from the two data sources, why are you worrying about this new data and a new method? Our answer to that question is that the BASF provides some advantages over the OACT file.

First, the BASF has beneficiary level data while the OACT is a county level file. Because of its beneficiary level status, we are able to analyze subsets of beneficiaries using the BASF which we can't do with the OACT file. For example, Shinobu will discuss regional variation in service use and prescription drug use combined. This requires a subset of beneficiaries that we could identify with the BASF, but we could not with the OACT file.

However, we believe that we are able to make more accurate health status adjustments at the beneficiary level than at the county level because the risk factors in the CMS-HCC are at the beneficiary level, as is the BASF.

Finally, the BASF has spending that is disaggregated into seven provider categories: Inpatient, skilled nursing facility, outpatient, physician and lab together, DME, home health, and hospice. In contrast, the OACT data are disaggregated into only two categories, Parts A and B.

The finer disaggregation of the BASF allows us to examine which provider categories contribute the most to regional variation. For example, last month David Glass presented findings about the effect that variation in DME, home health, and hospice has on variation for all services.

And now Shinobu is going to cover variation in drug use.

MS. SUZUKI: So I wanted to go over a few things about the data we're using and methodology before I go over the results. We analyzed the variation in drug use using essentially the same methodology as the medical service use that Dan just went over. But for this part of the analysis we focused on beneficiaries enrolled in stand-alone prescription drug plans, or PDPs, and this is because we don't have Parts A and B spending for beneficiaries enrolled in Medicare Advantage prescription drug plans, and we needed

both medical and drug spending to look at combined service use.

Medicare beneficiaries enrolled in stand-alone PDPs account for about half the fee-for-service population and PDP enrollees aren't necessarily representative of the fee-for-service population. For example, compared to all fee-for-service beneficiaries, a higher share of PDP enrollees are on Medicaid, and this is because when Part D benefit began in 2006, dual eligibles were automatically assigned to stand-alone PDPs. So the distribution of medical service use for this population is going to look somewhat different from what you saw earlier for all fee-for-service beneficiaries.

So we start with 2007 and 2008 Part D prescription drug events data. It contains gross drug spending for each beneficiary, which reflects all payments to pharmacies for the costs of the drugs, including payments by plans, beneficiary out-of-pocket, and Medicare's low-income subsidy that pays for cost-sharing for people with low income and low assets.

We convert the spending to a measure of drug use by adjusting for the factors listed here. Adjustment for

variation in prices across regions had minimal effect since unlike medical services where wages and other factors specific to the area may lead to substantial differences in prices of services, prices of drugs do not vary much across regions. We adjust for variations in population characteristics such as age, gender, and health status, and to adjust for health status, we use the health factors or condition categories from CMS's prescription drug condition category, or RxHCC model, which is used to risk adjust payments to drug plans.

We also adjust for low-income subsidy status and institutionalized status. The resulting drug use measure reflects both the volume or the number of prescriptions and intensity of service use such as a choice of brand versus generic drugs. We used essentially the same regression model used to analyze Parts A and B spending, as Dan explained earlier. In addition to factors listed here, the model also includes an indicator for each region to capture the region-specific effects not attributable to any of these factors.

So we wanted to see how much variation there is in drug use and how it compares to medical service use. For

the population we looked at, we found that drug use was more concentrated compared to medical use. For example, nearly all of PDP enrollees, or 98 percent of PDP enrollees, live in areas with drug use that's within 15 percent of the national average compared to 82 percent for medical service use.

We also found that for drugs, the difference between areas with high use and areas with low use were smaller compared to medical service use. For example, the area at the 90th percentile had 20 percent more drug use compared to the area at the 10th percentile, while the difference was 32 percent for medical service use.

We also wanted to see if areas that use more medical services also used more drugs. What we found is at the MSA level, there's no consistent relationship between the average levels of medical service use and drug use. But since these are aggregated across services and across beneficiaries in a given region, we don't think the results can be used to inform us about things like whether medical services and prescription drugs are a substitute for each other or complements for each other.

In the next slide, you see that combined medical

and drug use varies less than medical service use alone. For example, 91 percent of beneficiaries enrolled in PDPs live in areas with combined medical and drug use that's within 15 percent of the national average, compared to 82 percent for medical service use.

We also found the difference between areas with high use and areas with low use was smaller for combined use compared to medical service use alone. For example, the area at the 90th percentile had 24 percent more service use compared to the area at the 10th percentile, compared to 32 percent for medical service use.

So to summarize, as we found last year, service use varies less than spending and the supplies to all types of services, medical, drugs, or medical and drugs combined. We also find that there are large differences in service use even after we control for various factors that may affect the level of service use, and this is also consistent with what we found last year.

Finally, for beneficiaries enrolled in stand-alone PDPs, we did not find a consistent relationship between average medical use and average drug use at the MSA level. So we've listed here a few things for discussion. We'd

welcome any questions or comments on the presentation, and any thoughts on implications for policy.

You might want to comment on the future direction for this research. For example, we could further refine the work David presented on last month looking at DME, home health, and hospice, or look at other sectors separately which may shed some light on the sources of variation in service use.

We could also explore the relationship between medical service use and drug use by looking at a subpopulation, for example, looking at people with specific conditions. We're also open to other suggestions. That concludes our presentation and we look forward to your discussion.

MR. HACKBARTH: Thank you, Shinobu and Dan. Let me just pick up on the discussion questions and highlight one thing I'd like people to react to as we go through our subsequent rounds.

So one thing that we could do in this area is just try to refine the measurements, the research. So that's one potential activity. A second is to do that and to delve into the policy implications. People are aware that the

Institute of Medicine has recently created a commission chaired by Joe Newhouse at the request of the Congress, ultimately, to look at geographic variation and policy approaches for addressing it and assuring that high value providers are paid appropriately.

So we could either just limit ourselves to the analysis and trying to refine the analysis, or we could, in addition to that, delve into some of the same policy questions that Joe Newhouse's group will be looking at. My inclination is to do the latter, not to compete with Joe and the IOM, but maybe to complement what they do and maybe give them some ideas that they can consider during their work. So that's my thinking and I invite reactions among the Commissioners to that. So let's begin with our Round 1 clarifying questions starting on this side. Round 1 clarifying questions? Ron?

DR. CASTELLANOS: I'm really not sure if it's clarifying, but I really don't know what you're going to do with this data, but it's really powerful, some of the data that you can get. I would like you to look at the variation at the provider level. I think you can look at appropriateness and you also can look at the specific drug

use. I think that would be powerful information, too.

DR. BERENSON: Going back to last month's presentation by David, which was pretty powerful in documenting the importance of those three services, hospice, home health, and DME, medical service use variation, have you looked at medical service use in total and medical service use with those three taken out to see if there actually isn't much difference on pharmacy use versus those medical service use with those three services excluded?

DR. ZABINSKI: I haven't.

DR. BERENSON: I think it might be interesting.

MR. GLASS: Not yet. We're going to [off microphone].

DR. BERENSON: Because I do think then that the policy implications may be somewhat different in terms of -- this will be Round 2, but I think talking about where we go with all of this is important. That would be helpful to have.

DR. MARK MILLER: Can I get you to just say one more time, what was the drug connection in there that you were saying?

DR. BERENSON: I was saying, these findings show that the drug variation is less than medical service use variation and combined is less than medical service use variation. Is it less if those three services were taken out? Do you see what I'm saying? Medical service use minus those three services, is the variation pretty comparable to pharmacy variation, is my question.

DR. MARK MILLER: Oh, I see. Now I've go it.

DR. KANE: Just a quick one. So I notice that you only used the drug and medical at the regional, but are you able to link the Part B spending at the individual beneficiary level so that you can actually see whether they are substitutes or complements on all the other types of things we're interested in?

MS. SUZUKI: Yes.

DR. KANE: Good.

DR. MARK MILLER: Remember now, and I know you were saying I didn't think you could in the last session and I knew this would come up, but also remember where this linkage occurs. You're, in a sense, selecting a big. So number one, people who have the Part D data, make sure all this is correct, Shinobu, because I'm just trying to say

things that you've told me. And actually, if you want to tell this story, you could start right here.

MS. SUZUKI: I think one thing to remember is that Part D is about 60 percent of all Medicare beneficiaries. It's not all fee-for-service. We looked at PDP population, which is about 40 percent, that's half of fee-for-service population. So we're going to have some selection issues.

MR. ARMSTRONG: On Slide 3 you talk about the underlying methodology that you use and admittedly, I don't know very much about some of the various adjustments that get made for prices, special payments, and so forth. My question is, do we ever check to confirm and affirm our confidence in the methodology for all those acronyms that make these adjustments?

DR. MARK MILLER: Okay. So I think one way just to cast your question is, if we went in and adjusted for the wage index, if the wage index was somehow flawed? I think there's two answers for that question and I'll absolutely take any help that anybody wants to give. Sometimes they just leave me out here, so I like to say this up front.

The two things are this: When you're going back in time and looking and saying, I'm trying to figure out how

many units in the utilization was provided, in a sense, what you should do is use whichever adjuster was out there, because right or wrong, that's how money was allocated, and if you're trying to back out the effect of the wage adjustment, you use the one that was in place at that time in order to back in to the utilization.

It's sort of a policy question going forward which says, But wait a second, the GPCI values for this component weren't particularly well constructed. We sort of consider that on a going forward and should we think about adjusting and changing those bases. But if you're just going back in time and looking at the utilization, I think methodologically you should use what was in place. Otherwise, you'll be introducing another variation that wasn't necessarily present in the past.

So I think your question has important methodological implications. I think you're stuck going in the past even if something is wrong, but it may mean that you need to identify something and fix it going forward.

MR. HACKBARTH: So there should be no implication drawn when we focus on service use, that the implicit message is we think all of the payment adjustments are

perfect and right? We're just trying to set that set of issues aside and look at patterns of care and how they vary across geography.

MR. ARMSTRONG: Thank you. I understand that. Is there any reason, or is it really within our jurisdiction, to be concerned about the methodology as we look forward as a matter of policy?

DR. MARK MILLER: Yes, absolutely, and this Commission has made -- just quick things -- made a series of recommendations in reforming hospital payments, the wage index for the hospital payments. We've made spot comments on ways to improve the GPCI, the special payments whether they're rural, teaching, disproportionate share, and much of that often comes into play later in the fall when we start doing update and start thinking about equity of payments. Often it comes up there. But yes, and it can come up anywhere if you have ideas that you want us to pursue.

MR. HACKBARTH: In fact, the vast majority of our activity is directed at looking at the different payments systems, identifying ways in which they're imperfect, and ways to improve them.

MR. ARMSTRONG: I have so much to look forward to.

MR. HACKBARTH: You do, you do. Just can't wait, huh? Kate?

DR. BAICKER: In my own small work looking at the substitutability of Part D for other Medicare spending, the correlation between those two seems very sensitive, in particular, to HCC adjustment. And so, I wonder if you've looked at how sensitive your results are to that particular adjustment given the endogeneity issue that was raised in the last discussion.

MS. SUZUKI: I think we found things that were consistent with what we've seen in some literature, that prior to adjustment for various factors, it's not just HCCs, the correlation was actually pretty high, I think, on the order of maybe .6-ish. I think correlation is much lower once you adjust for the demographic variation than health status.

DR. BAICKER: But I'd like to actually separate out the demographics from the health status because I think the demographics are not endogenous, you know, that physicians aren't differentially coding people as male or female in different areas. But then I think that the risk, the HCC, is endogenous, and so you're capturing both health

status and practice patterns. Whereas, the other demographics seem more innocuous.

DR. STUART: Let me just give you one statistic and then I'll come back to a point that Mark raised. We've done some work looking at or starting with diabetes and looking at the proportion of people, Medicaid beneficiaries, this is 2006-2007, who have a diagnosis of diabetes by the coverage status that they have under Part D. So we're comparing Part D enrollees with RDS and creditable coverage and then no coverage.

What we find is that about 25 percent of the Part D enrollees and 25 percent of the RDS enrollees have a diagnosis of diabetes. It's about 21, 22 percent for creditable coverage. And for people for whom they may have some drug coverage somewhere, but it's not creditable coverage, we assume that most of them don't have drug coverage. And for that group, the proportion who have diabetes is 12 percent.

So it's quite clear that there is selection into these drug categories based upon having a very prevalent disease, and we haven't done this yet for all of the other conditions we're going to eventually look at, but I just

raise that as an issue. And, Mark, you're absolutely right. That is something that does need to be taken account of.

As far as risk adjustment, this is almost never ending, and I don't want to take a long time on this, but I do have a semantic issue with the term raw spending and then service. Now, technically, we're not counting services, and we're not counting them because we can't do a perfect adjustment for all of those other factors. I recognize that.

I suspect that instead of raw spending, though, what we're really more interested in is probably something that I might call medium rare spending, which -- and the reason for that is that there's a theoretic problem with controlling for price, and it's this: In areas that have high reimbursement relative to the national average, we would expect that providers have an incentive to provide more service.

And so, if we control for price, we're also controlling for price response for services that are provided as a result of those price differentials. Now, that might not be a big deal for the hospital wage index, but it could be a big deal for physician service -- you

know, for other kinds of prices.

So I just raise that, and when we talk about these things, when we talk about services, we do have to realize that not only do we have the problems associated with adjustment for these other factors, but in the fee-for-service sector, we're not just paying for services in the sense of actual physical things. We're paying for buckets of stuff.

So we're paying for DRGs. Well, what's a DRG? A DRG varies depending upon the patient, so it's not just services. So thinking a little bit about what that means and then I'll come back. I have a couple of other things in the second round.

DR. BORMAN: Just a quick question. You mentioned IOM activity in this same area. Could you remind me what our obligations are, if any, to interdigitate with them and/or comment specifically once they're done? I mean, my recollection was that the Secretary was -- it wasn't legislated to form this, but was encouraged to have IOM study these two things and then is encouraged to use the results. Was there anything in the middle of that that we were to comment on or more interdigitate in some mandated or

formal way? I'm just mixing up all the things we've been charged with doing.

MR. HACKBARTH: So this is not a statutory provision any longer. There was a provision in the reform law, the House bill, that called for the IOM study and had language in it that said that IOM should give the report to MedPAC for comment, as I recall.

DR. MARK MILLER: That's what I'm struggling to remember. I'm pretty sure the legislative language referred to consultation with us. I can't remember if it gave a specific directive to review and comment on the reports coming out of the IOM.

MR. HACKBARTH: Yes. In any event, that was stripped out of the final bill, and instead the administration offered sort of a side agreement saying that we will go ahead and ask IOM to do the two specific studies, the one on the input price adjustment and then the one on geographic variation. So there's no governing statutory language.

Now, Mark, leap in here. In point of fact, there has been some discussion. Mark went over, for example, and presented our work on service use. You take over.

DR. MARK MILLER: There has been a lot of discussion from actually even just the creation of -- just the staff asking us for our past work on wage, GPCI, that type of stuff, for the one panel, and the staff asking us, on the other hand, give us all your work, which, you know, is public and we direct them to it, and little conversations about how we do things like this.

They asked us -- and it was myself and Jeff and Kevin and David who went over and talked them through the hospital wage index report, and I expect at some point they'll probably want us to walk them through this report, even though, you know, they'll have copies and all of the rest of it. So far that's kind of where it stands.

And I think Glenn's point is that I think they're interested in our view. You know, whether they embrace them fully or at least consider them, they're interested in our views, and I think that's why Glenn would like to -- there's methods and data and all that, but would like to use this session -- if we have views about how this information should be used, I think he's trying to solicit that.

MR. HACKBARTH: Right. Just at a personal level, Joe Newhouse is the chairman of this commission. He's a

former Vice Chairman of MedPAC. Gail Wolinsky is on it, and Gail's a former MedPAC Chairman. Bob Reischauer is on the commission. So, you know, there are lots of personal connections in addition. You know, I think that they are interested for whatever information or thinking we can provide them.

Just one round one question. Would you put up number 7, page 7? So in the left-hand axis, the vertical axis, what is the region, the unit, the regional unit there?

DR. ZABINSKI: It's the fraction of the total population that each region is.

MR. HACKBARTH: And what is the region?

DR. ZABINSKI: There's 409. They're like metropolitan -- MSAs for urban areas, and the rest is state areas for non --

MR. HACKBARTH: I just needed a reminder of that. Okay. So round two

DR. CHERNEW: So first let me say I support your inclination to try and do some policy stuff from this, and in that regard, I'll say this has become a very inflammatory area in part because of the work that Dartmouth did and the reaction to it and various things. And so interpretation-

wise, I think my general view is one can quibble about exactly how much variation there is and how much variation goes away when you make different adjustments, and the endogeneity or not of those adjustments, much of which I think will be hashed out in academic literature, and deservedly so.

But I think it is implausible to assert that there's not meaningful service use variation. Certainly when you get into some of these other areas that David talked about and DME and stuff -- and I think we can learn something with that. So my personal view is, well, we can try and figure out how to quantify exactly better -- and you've moved it, you know, from 29 percent, 90th to 10th, to 27 percent, 90th versus 10th. And if you switched to different measures of geography, you could get more or less variation in a different year. I think that's actually probably not where I would spend most of the time. I think understanding not where the variation is but where the waste is, thinking about how to integrate that with, say, some of the things when we're talking about SGR, is there waste that we can clearly attribute to something that we could then get out of I think is much more fruitful than trying to spend a

lot of time getting the -- I think someone should just assert there's important variation, we have to worry about the variation, and quantifying whether it's, you know, 30 percent or 20 percent strikes me as less of a value-add for us to do is what to do about trying to make the system better.

MR. HACKBARTH: Help me, Mike. I'm a layman. But one of the things that strikes me about this debate is that so much of the discussion to this point is about comparing the 90th and the 10th percentile, so it's the range in the distribution. But it seems to me equally important is how much clustering there is in the middle. And as I look at our service use numbers, 90 percent of beneficiaries are in regions where -- plus or minus 15 percent of the national average. So, you know, we're talking about the same statistics, but what do you focus on? The extreme values or how much clustering there is around --

DR. CHERNEW: But even in that case, if you go to the plus or minus 15 percent, so I could take those same numbers and say, all right, I'm going to take the bit that's at the top -- there's a 30-percent range difference between the plus 15 and the minus 15. So I think a lot of this

debate is just how you want to project --

MR. HACKBARTH: Yeah.

DR. CHERNEW: It's how you use that statistic. So I agree with that statistic. But is the point of that statistic so regional variation doesn't matter, which you could say that, but I don't think that's what you mean to say. That's not what I would take from this literature. I would just take the general point there is variation. You can take many of the statistics and frame them in ways that make it look like a lot by looking at 90th/10 or 95th/5th. You know, if you just take the tails of any distribution, it looks bigger. The question is, there's inefficient use in different places, and we might be able to figure out some of the reasons why and how to deal with it.

MR. HACKBARTH: Yeah.

DR. CHERNEW: I think it's the broader qualitative point about variation exists, does it matter or not, as opposed to figuring out what the right metric of it is and then quantifying according to that metric. That's my general view.

DR. BAICKER: I'd just like to jump in because I think there's a point here. I actually agree with you about

not getting into the weeds about exactly how to calculate the different adjusters. There's a first-order question of are you actually picking up practice style that points to a different source of the waste. So the goal is to focus on the variation that you think is being driven by inefficient use. There are second-order things that we're never going to get right. I think understanding the way people's health is categorized could actually be a first-order thing that changes the story about the correlation between medical spending, home health spending, Part D spending. If you mis-measure those interactions, you're going to have a very different picture of the waste.

DR. MARK MILLER: You know, the way I think about that, because you made that point also in the first round, is -- because I think -- I've been trying to think about this, too. One way to think about that -- and let's take HCC coding because that's clearly one of the examples. One way to think about that is which way does it bias the estimates. We think that it probably means that, if anything, we're understating the level of variation. And so one way to deal with the kinds of issues you're raising are do you solve them and methodologically spend your time

trying to sort through it, or at least understand which direction it might be driving your results. And I know you can think that, too. I mean, I know you get that.

But I think a point -- a different way to state Mike's point is that if you spend -- and I know you're not making this point. This I think is more just to amplify his point. If you spend a lot of time sorting through and let's explain all of this, you may be pulling out chunks of variation that as a policy you want to deal with.

Let's just pretend we could quantify self-referral perfectly, and then you dropped it in as an explanatory variable, the level of variation would go down. And so you would say, see, there's less. And let's just say it became tiny. But as a policy, you as a Commission might want to say, Wait a second, that's not necessarily variation I want to tolerate. And so you have to be conscious that as you go through and drop things in here, are there things you want to control, as Kate is saying, because you want to be sure the picture is correct, or things you want to actually deal with as a matter of policy. And I think that's implicit in both of your comments.

DR. CHERNEW: And I guess what I would say is

focusing on type of service, like David's DME stuff, that's, I think, useful and one could discuss all these issues there, but my guess is I'm pretty convinced there's a lot of meaningful variation in that type of thing, and we should look at it. And I don't need to quantify exactly how much to know whether to look at it.

Figuring out type of patient, is it in these types of patients or those patients? Another thing that would be useful to know where to look.

But I guess my point is for our work as opposed to a lot of the other work that will undoubtedly go on, getting -- we can have a discussion about how far to get on the methodological purity -- right? -- but I tend to think that a lot of that's going to get hashed out in a lot of settings, and doing a good enough job to point the magnifying glass is what we have to do, not get it exactly right. That's my general [off microphone].

MR. HACKBARTH: The question that I'm struggling with -- and I welcome reactions to it -- is as a layman I'm still not sure whether this is a lot or a little variation. And to me, that is an important thing in deciding how much you want to invest in policy changes to address it. So I

welcome reactions on that.

DR. NAYLOR: So I walked away, I don't -- this is their world so I don't know it, but I walked away with this message: Less than 2 percent of people live in areas where they have -- where it's 25 percent more than the national average in terms of service use. So I thought the message was there's not much variation in service use. There is in spending. You know, so I don't know -- I walked away saying that there wasn't much variation based on this report.

MR. HACKBARTH: We certainly have a policy debate that's been driven by, Oh, there's a huge amount of variation and we ought to do something about it. If only we could. But that's not clear to me from the --

DR. CHERNEW: Let me just say, part of the problem with those things is if you add all the things back in like you've done, you get a bigger mean, so 2 percent is a bigger number. So there are going to be enormous, really important variation in DME or other areas, but it's not going to rise to 2 percent of the total because you made the total really big. So a lot of this is the way in which the numbers are being reported can lead you to think they're big or small. So I'm just trying to say I think they're meaningfully worth

going at in sub-areas and the rest of it's just how you want to characterize it in a debate that I think is less important.

MR. BUTLER: Okay. Certainly we should proceed and get ahead of or parallel to IOM, partly because we have great staff and momentum on this, anyway. So that's my comment on that.

Second, you know, this is just an aside. We keep calling these things "regional" variation. I wish we would say "geographic" variation or something different -- "regional" kind of has -- it gets into the congressional -- you know, I'm moving money from one region to another as opposed to geographic, which could be down to a zip code level. That's just an aside.

So kind of picking up on Bob's comment on with and without the DME, home health, my ideal database would look at this with three variables in mind: one would be the geographic, which you could build up from even a zip code level, maybe; the second would be our payment silos, so you would take every one of the ones that we act on in December or January, and you would -- and all this would be service versus price; and then my third variable would be get back

on the episode kick.

So that you could really kind of look at a set of data based on service that you could look at a geographic, an episode, or one of our payment silos. And if I had that in front of me with the total for an area, I think it would help inform even the payment updates in a little bit more robust way than how we look at it now, which is, gee, you know, the profitability and all these other things.

I have no idea how hard it is to pull that data together, but I think it links to our payment silos in a way that would help inform our payment updates in a different way than we're doing it now.

MS. BEHROOZI: I don't know where this goes in this whole debate. I'm feeling like the more I listen, the less of a handle I have on, you know, what long ago seemed confidently a topic that we needed to attack kind of thing. And just one of the things I wanted to highlight was the lack of correlation where you talk near the end of the paper about McAllen, Texas, you know, being at the very top in service use spending, or service use spending, all of the above, but 305th or something like that on the drug side.

What does that mean? What lessons do we draw from

that? You know, these are all very -- it just reflects back to me that health care spending is local and practice patterns and all those other things are very local, and it's also different by area. And so, yeah, maybe more work in all of those different areas will begin to put the picture back together.

MS. UCCELLO: Yeah, I'm getting more confused the more I hear, too.

MR. HACKBARTH: [off microphone] You're our actuary.

MS. UCCELLO: Yeah, so we're all doomed.

[Laughter.]

MS. BEHROOZI: Okay. Turn off the mic.

[Laughter.]

MS. UCCELLO: Turning back to what Glenn was saying, well, what are we considering as something we think we need to deal with or not and looking at these charts that -- you know, I want to know what kind of how much these vary by kind of the different underlying services because I think they inform the types of policies that we would want to pursue. If things are clustered, then maybe the pricing is appropriate and we want to attack the outliers with certain

types of options. And so the question is, you know, do these -- how much do these patterns look similar across the different underlying services?

Then I want to key off of something that Bruce said about prices and prices influencing behavior. I think that's important, and when we think about that, then we also need to think about the pre-65 pricing and how those markets are working, because that can influence the behavior in a community more than just the Medicare pricing.

I hope I redeemed myself a little bit.

DR. CASTELLANOS: I was going to say I'm looking forward to getting home and practicing medicine. It's a lot easier

DR. BERENSON: Let me take a few moments. As one of the protagonists in the sort of Dartmouth debate, I actually think in recent months there's beginning to be a confluence of a number of different studies, and I think MedPAC's work is right in the middle of all of that, that there is significant variation, not as much as Dartmouth initially had estimated once you do the adjustments, but whether it's population-based studies or studies at the individual level, it shows significant -- I'm with Mike. It

shows significant geographic variation in service use.

I think there's still an issue that's worth studying whether we can explain the variation or whether we can't explain the variation, and I think there still is some disagreement about whether supply is one of the important explanatory variables or not. So it's important for people to continue to do that work, but I think we have a growing sort of agreement about a general level of the variation. Is it significant or not? I think it is. We are trying to -- we could stabilize the whole health care system if we bend the curve by about 2 percentage points of spending each year. And we're looking at variations in the 15-, 20-percent range. And we think, at least, that there's no significant quality differences, so it seems like there are some opportunities, and opportunities that do not involve the R word, rationing -- in other words, responsible policy. That's a large pot of money that, if we can figure out some policies, can help us get costs under control without compromising anybody's care. So I look at that as it's real and meaningful, and it doesn't mean we're indicting anybody for bad practices. It doesn't mean I would be looking at policies through the lens of geography necessarily, that I

would penalize or reward based on geography, and, in fact, I think there was a chapter in the SGR report that MedPAC did in which MedPAC looked at geography and I think raised some concerns, and a number of the articles, papers that have been published on this issue have taken sort of stabs at what would the policies be.

So I think there's -- so I'm not thrilled, but I think we want to talk that through. I think we should get on with it then, agree on we don't have the exact quantitative number, but with Mike, I would say it's significant and we should start systematically trying to figure out what to do about it.

MR. HACKBARTH: Bob's comment reminds me of one thing that I think is useful to always bring up when we talk about this. For example, in the first service use analysis that we published a year or so ago, one of the things that we did was point out -- we looked at the variation across the country, and then we had some statistics on the variation within smaller geographic areas, and as I recall, one of the things that we did was look at a state level, and there was as much variation within the State of Iowa as there was in the country. And so I think that's just always

a good reminder to throw out to people because there is a lot of this talk that, oh, there are certain states -- you know, in our political world, there are certain states that are more efficient than others. Yet when you look behind the data, there's huge variation there.

DR. KANE: I think there are certain MSAs that do cause some concern. I seem to remember maps where southern Florida kind of leaps off the map. But apart from that, I think this stuff is really interesting not so much because of the measurement -- I mean, once you get a measurement that's reasonably acceptable, as Bob is assuring us that it is starting to be reasonably acceptable, how do you use it to understand where the opportunities are? And I agree with Peter, we should be looking at this by both the provider type and also by -- I'd like to see it by certain types of diseases. In particular, it would be interesting to know if the bottom 25 percent treat the major disease classes in a different pattern or pathway. You know, how is it that you end up in the bottom 25 percent? And instead of looking at the outliers, you know, we often as researchers just like to look at the bottom quartile and the top quartile and say what are the big differences between the two quartiles --

these are big groups of patients -- and try to see, you know, are they handling the post-acute sector differently or don't have the LTCHs in the community. You know, we'd like to sort of understand to better understand what makes them that way rather than whether they are that way. So I would like to get much more into what makes them that way.

The other thing that rings a bell -- maybe I've just been going to too many MedPAC meetings --

MR. ARMSTRONG: You're hearing bells.

DR. KANE: Yeah, a lot of bells, a little ringing in the ear. But at one point we were talking a lot about MA plan benchmarks and the variability by high-cost and low-cost areas and what would be a reasonable way to try to make these benchmarks less variable across -- and so to me there are some pretty important things to understand about why there's that variability, and then should some of that, in fact, be put into recommendations on how benchmarks get set, because we did -- I just remember graphs of things like -- some went like that and some went like that, and some had floors and -- about how do you understand -- you know, how should we try to reduce the variability in the bench -- or whether we should around MA plans.

MR. HACKBARTH: [off microphone] whether you should.

DR. KANE: Whether you should, and then, again, this could inform some of that discussion, and then if you should, in what ways and why.

So I think it's very useful, but I'm done with trying to pull out -- you know, explain the variation. I'm more interested in seeing, you know, what can we learn from the different buckets that the different areas fall into.

DR. MARK MILLER: Just a little commercial. I can't remember whether it's next month or in December that we're going to block through some of the MA stuff. Next month. So actually hold that -- I mean, hold it or not, but that thought will come back, and you'll see some of what the reform legislation did, and it does relate to some of this variation. So you'll get another shot at this next month.

MR. ARMSTRONG: So, Glenn, I would just briefly add that some of you know over the last couple of years I've been a relatively outspoken and passionate advocate for getting into this geographic variation and understanding it better, but remarkably unencumbered by much information. And so I would really strongly affirm the value that several

of you have expressed in the work that we do to go forward with this. Particularly as so much other work it does seem is coming together, I think we can contribute to not just deep analysis but actually insight into what are some of the policy implications of this.

MR. GEORGE MILLER: Just briefly to echo what already has been said, but I like Peter's -- first, let me back up and say using Mary's statement yesterday about knowing what the total budget is and then using Peter's framework, instead of doing the silo analysis but look across the entire spectrum, and take into consideration what Mike said about the variation, even the 15 percent plus or minus is 30 percent, and that's something certainly to look at.

While I would agree we don't necessarily need to look at geographic variation, I am struck by places like McAllen, Texas, and the statement Mitra made that they're number one in service but 350th in drugs. I'll make a small joke. That's because they have their own drugs. But that variation is different. That may not have been a good joke, but --

[Laughter.]

MR. GEORGE MILLER: I'm going to get a lot of letters probably. But that variation at the extremes is something that we could study what not to do or I think we could learn from that versus looking at the variation. But, again, going back to Peter's point, I think we should line these all up and look at them, and instead of taking each side, determine based on profitability or non-profitability, but look at who's doing a better job at providing care on outcomes by diagnosis or disease versus just a provider getting X number of dollars or not getting X number of dollars.

DR. BAICKER: I liked Mark's way of characterizing it a lot, that the goal is to display the information and analyze the information in a way that lines up with our policy levers, and that means not controlling for stuff that we think are the policy levers we might want to pull, and then lining things up, breaking things out to show us how particular policy levers, whether it's payments or bundling, feed into the geographic variation that's the symptom, not the problem. So getting really detailed, nuanced measures of exactly how much variation there is is less important than saying here seem to be the policy levers that are most

closely associated with some places spending a lot more money than others with no effect on quality; and getting a complete picture of that by combining drugs and all these other categories gives us a more nuanced view of which policy levers to pull.

MR. HACKBARTH: Do we have empirical evidence that changes in incentives reduce variation? Just to be concrete, say we went to per case payment for hospitals, did that reduce variation in hospital costs? Has anybody ever looked at that? What makes me think of it is, you know, if, in fact, we look at variation and change payment policy in areas where we think there's a lot of variation that may be inappropriate, do we know that that actually works to reduce the variation?

DR. BAICKER: Have we seen stuff from --

MR. GEORGE MILLER: The state --

MR. HACKBARTH: Well, we know -- what I know is that length of stay in general went down. It went down everywhere. I don't know that, in fact, variation was reduced.

DR. CHERNEW: For outpatient it went up, but more importantly, do you care if variation is reduced or length

of stay goes down? In other words, you could reduce variation by raising all the low places. That's not the goal. So I think the valuation of the DRG system or whatever it is has to be comprehensive in terms of its impact, not just what it did on -- variation in and of itself isn't the best outcome measure. We want to get places to the right place.

[Pause.]

DR. DEAN: I was just going to second Ron's comments, first of all. But the thing that occurs to me, being a bit overwhelmed by most of this, is that I wonder how small a unit do you have to get down to, to really understand this. And I suspect it's almost down to the individual provider, whether it's a facility or a physician or whatever, because there is so much variation.

Now there may be trends within a given community, for instance, and we know that community influences ordering patterns. But even within relatively small communities you see a lot of variation.

MR. HACKBARTH: In fact, it's always struck me as ironic that my first recollections of Jack Wennberg's work was that it focused on large variations across very small

geographic areas, and now we've sort of gotten to focus on variations across much larger geographic areas.

DR. DEAN: I think in the McAllen, Texas article there was a community -- was it El Paso -- that wasn't that far away, that was dramatically different, if I remember, and those are fairly big. Those are fairly big communities. I suspect within those communities there is variation, although maybe not a lot.

DR. STUART: I share the frustration here because I think what we really are looking for is a road map in terms of how we use these data, and I guess I'd throw that back to you, Mark, and to the staff in terms of trying to develop that. How you would use these measures, these metrics if they are in fact right, I think is very important. I'll give you a couple of examples in a minute.

But I disagree with Mike on this, and I think it's fairly fundamental, and that is if somebody questions our metrics there's no sooner way for somebody to attack the credibility of our findings. So we have to be able to say that our metrics in fact are accurate, are presenting information, that we understand what the variation is due to, even if that sounds like an academic exercise because

all somebody has to do is to come up with our number and say well, I don't believe your number. Then whatever policy comes from that number, you know. You're just destroyed. So I think that's something that we've got to do.

DR. CHERNEW: I'll just say we would spend years, and I think we would never get to a metric that would be able to be unassailable.

DR. STUART: It's not just the metric. It's the way you get to the metrics, and the ingredients in that are important. And we haven't had that discussion here, and I think that's probably something we can have at the staff level, but I think it's really, really important.

As I said, and I think Cori picked up on, if you don't control for the fact that prices induce behavior and it's price-induced behavior that may in fact be one of the problems associated with payment policy, then that's a pretty serious issue, and it's something that you'd want to take a look at. If some of the variation in spending is due to provider response to prices, either high prices or low prices, then that is something that becomes part of the gist of our discussion.

That's not risk adjustment. That's behavior you

want to pay attention to.

Let me get into the other part of this that I think two things that I'd like to see. I like this graph, but I wouldn't do it. I'm not particularly interested in total spending. I want to get down to the Part D side.

And you've put PDP data and MA-PD data together, and then you compare it to total spending for Part A and Part B in one chart. Then you do it, and you just do it for PDP. You don't want to combine the PDP and MA-PD and then just compare it to the Part A and the Part B because what you've got is that in one sense you've got the variation associated with people who are in MA plans, on the drug side, but only variation associated with the Part A and Part B on the other side. So that's a real apples and oranges kind of comparison.

So I'd like to see one that looked at variation in Medicare spending and Part D spending, but even more important I'd like to see variation in MA-PD drug spending and PDP drug spending.

And you're absolutely right. It's not just variation. I want to know the point estimates. In other words, I want to know what the mean is for each of those two

and how the distributions overlap.

And I have some hypotheses. At least on the MA side, I would hypothesize that the spending might be a little bit higher on drugs. To the extent this gets to my second point, to the extent that spending on medications for expensive chronic conditions and for which are designed as secondary preventive services, part of the idea here for having Part D is that this is going to increase drug use, keep people healthier, reduce spending on hospitalization and other bad stuff. Well, you know we don't know, but that's a really important issue, and so it would be interesting to move in that direction.

The second thing, and this is I think where you're going, but I'd like to hear it, is you said there's no correlation between drug spending and overall medical spending. That's exactly what I would have expected at the aggregate level.

You used the terms "complements" and "substitutes," and those are exactly the terms that I would want to look at. And drugs are obviously both. In other words, you have to visit the physician to get a prescription, so physician services and prescriptions ought

to be positively correlated.

If there is some cost offset, that would be a substitute; that would be a negative correlation. So you clearly have both going on together, and I think what you're saying is when you see no overall correlation it's probably that they are offsetting to some extent. So how are you going to be able to differentiate them?

And I think here you probably do have to get down to the disease level. You have to make some more specific hypotheses about drug use for treating diabetics or heart failure patients or COPD, or whatever it might be, and see whether variation in one has an impact on variation in the other. Then we're really moving in the direction of getting some real red meat that we could use to help us in terms of making policy, in terms of how we price products that we think are going to be substitutes, particularly if they're cost lowering as opposed to those that might not be.

DR. ZABINSKI: I have a question, Bruce, and I hope I'm not embarrassing myself. Actually, I don't care. I do it all the time.

[Laughter.]

DR. ZABINSKI: When you talk about the incentives

and price, are you talking sort of like accurate -- how to say it -- accurate adjustment so that either the adjustment that's made, like with the hospital wage index, accurately reflects the local costs in the area, or is it more of a nominal? Like the places that have really high hospital wage indexes, there's an incentive to provide more.

DR. STUART: Well, I mean it's almost Econ 101 in the sense that in order to identify what the demand curve looks like you have to also estimate a model that controls for the supply because supply and demand together are what determines price. So to the extent that you have areas that high price is that a function of high demand, or is that a function of the providers responding to price signals?

DR. MARK MILLER: Dan, the way I think about this is remember some of the Hadley stuff, when he comes in and kind of talks about price and the incentive that price is above the average.

I think there are two issues: Did you geographically adjust properly? Then there's just, to use your terminology, Econ 101. What does price do to demand?

And I think it's more like that Hadley stuff that he has come in and talked to us about. You know the stuff

I'm talking about? I think that's what he's saying.

DR. ZABINSKI: As you were talking about it, I mean -- okay. Some of the highest lowest use areas are the Bay Area of California, and that's also some of the highest price areas though. And some of the highest use areas are in Texas and other places in the Deep South where the wage indexes are quite low.

DR. STUART: No, I'm not saying that it's one for one. I'm just saying that if you adjust, if you get rid of all price differences, you're also going to get rid of some real behavioral responses to price at the same time. There's a baby in the bath water kind of issue here.

DR. CHERNEW: But the thing is of course is this is Econ 102 because people are insured, so there are two prices. Right? There's the price that the person is paying which is the demand curve. Then there's a supply-induced part of the price which is what Bruce would say, and that depends on not just what the price is, but the prices relative to the input costs. And the input costs themselves are potentially fungible and substitutable. So I actually do think it boils down to how mispriced the wage indices and the other geographic practice price indices are, as to

whether or not that's dealing with it.

But I think in general all this literature can just point us in areas, and it's going to take a lot more to get at the causal. So once you identify the variation, then you have to begin to dig and ask all these other questions.

DR. STUART: Let me respond in your own words. If you're right and I'm right, then it means that the true variation is somewhere between the raw spending difference and the "service" difference. It's somewhere in between.

DR. CHERNEW: [off microphone] [inaudible] you mean by true variation [inaudible].

MR. HACKBARTH: I have a question. Ron, is it too late for me to go to medical school?

[Laughter.]

DR. CASTELLANOS: [off microphone] You're much too smart [inaudible].

MR. HACKBARTH: Karen.

DR. BORMAN: Well, if I were truly wise, I would probably emulate Tom and Ron in this and just shut up right now, but if you look in the dictionary I'm not sure my picture is under "wise." So I'm going to make a stab at just a couple of things because I can't get into the nuances

that some of you have put into it.

Some of the things I like and dislike about this, from sort of, as Glenn says, at a lay level, just how much does this matter and where do we go with it because I have been interested in this, and Mark graciously took a fair amount of time with me on the phone to help me understand it a little bit better.

I think I would disagree, Mike, that the number doesn't matter. I agree with you that maybe the bigger importance is the qualitative piece, but I think the number does matter. And I think the reason the number has mattered is because it has been ballyhooed in such a way as to be the silver bullet that we all wish we had, to be able to afford all the health care we wanted for everybody in the country, whenever we want it, with the highest technology and whatever. And I think it's important to disabuse ourselves of that notion just a little bit.

I think Bob's point that if we get part of the way that we do some real good is also very important as maybe the counterpoint. But I think we need to make sure that those things are out there, and I think that's why it is important, to me at least, in understanding this.

Is it 30ish percent versus is it 15 percent? Because to me 30 and 15 there, a factor of 2 there, that does kind of have some -- that's a number I can understand. I don't write checks for $450 billion, but a factor of 2 I can understand. So I did think it was important that we establish that.

I have a gut positive feeling about the fact that two very elegant analyses came pretty close. At least in my world, when you try and get the value of a drug or an operation, or whatever it is, and you get some studies that start to come out together, particularly coming from somewhat different directions, it kind of makes you feel good about it, and that maybe it is more valid. And maybe that's just my Statistics 101 failure, but I like that part, and I think we've established that.

I think there is a question. We have our big toe in the water, and it's clearly proven to be a somewhat piranha-laden water. I just am not sure whether I want my whole body to go in the water now.

[Laughter.]

DR. BORMAN: So I do think that we need to be really careful where we take this.

I like Mark's thought about, and it has been echoed by other people, what is it that it tells us about when we take things out. What does it tell us about those, and does it help us to identify the importance those? And maybe those are the places where we can make a difference, and maybe they're not.

I think there's real danger in getting down to too much detail, for example, if you went on the disease basis. Twenty years ago there was a major hoo-ha in breast cancer treatment about that women were being poorly treated if they weren't absolutely offered breast-conserving surgery, if they were advised to mastectomy or they had a mastectomy, and just the crude rates of who had breast-conserving surgery and who didn't were compared. The implication was certainly quite strong that those who had a mastectomy were bad doctors or getting bad care. When you dug into it in reality, it somewhat related to the distribution of radiation oncologists because in order to get breast conservation you had to get radiation. Otherwise, your outcome was not as good.

So there is a way. This just gets so context-sensitive, that I'm just concerned that the more detailed we

get here the more we're going to get hung up in more things we don't understand. And maybe there are some categories that folks like staff, and Mark and Kate and Cori are smart, and Peter, are smart enough to pull out of this.

But I just worry that we need to stick maybe to more generalizable things like the policy pieces, and those relate to the qualitative point that I think Mike makes, which is very important. There is variation.

The point that Bob makes, that if we do even something about it, it's a good thing, but we need to be careful about how and what we identify as the things to do something about based on these.

I also think we need to remember that there are other things flowing along in the river at this point, that if comparative effectiveness moves to where we want it to be, that will be another way at getting some of the variation here that we don't have the power and the smarts to say is right or wrong, like that clinical example I gave you. We're not going to get there through payment, but through comparative effectiveness I think is our opportunity.

Then I think another thing here is what we haven't

talked about. This is all assuming that it's a normative distribution and that the mean is maybe where we want to be, or even the 25th percentile. Remember we're all supposed to be thinking about that efficient provision. So maybe the discussion here is whether we look at it by the silos or the carve-outs, or whatever, that we try and identify.

And we've done some prior work at saying what we think are high-performing systems and efficient systems, and to start compare, use that as the matrix or the format or the structure for that comparison because that gets us more goal-oriented, at least in my understanding of this and where we want to go with this.

So those are the things I think.

One other thing that Mark said that I thought was hugely important is every time we do this as we have done, I'm not sure others have always done, is to make a statement about where we think our biases could be and what they would do. As Mark has pointed out, the way we do things is more likely to underestimate than overestimate. But there may in fact be other ways to come at that are more likely to overestimate.

And I think every source in this discussion,

whether we invoke it in what we do, should comment on that subject because I think that that is important to the interpretation of this and at least is something that, in my very simplistic economic and statistics level, maybe helps me to figure where are appropriate ways to go. So, just some thoughts on a kind of less detailed level.

MR. HACKBARTH: So here's a thought that I have. Listening to all this, only 10 percent of which I understood, it's complicated to use this analysis to identify positive policy prescriptions. You know, here's what you do affirmatively because of this analysis. That's a difficult task.

Maybe we can make a contribution by saying here are some widely discussed policy ideas based on geographic variation that you wouldn't want to do, sort of rule out things. Even if you can't say here's really what you should do, at least maybe we can say here are some ideas that you really don't want to do because of this analysis. And that might be a contribution even if it's sort of a negative one.

MS. BEHROOZI: I was thinking maybe it's just easier to show what it isn't than what it is, kind of like when MedPAC stripped out the spending factors and showed

service use was different and it wasn't about service use.

Yes, and that makes me think about outliers. You know, maybe there's a reason to focus more on outliers. We kind of keep throwing them in sometimes. But maybe that's like McAllen, Texas is an outlier when it comes to non-drug related spending, and there is some evidence of why that's the case -- because of certain entrepreneurial activity, maybe by physicians, physician-owned hospitals, those kinds of things that we do talk about specifically.

Maybe that's a better contribution that we can make in home care and hospice and places where you see outliers, and you can kind of identify why they're outliers, which also relates to the lack of correlation because they might be an outlier on one thing and not on anything else. So it's not about the overall in that area.

MR. HACKBARTH: [off microphone] I was just saying thank you.

[Laughter.]

MR. HACKBARTH: Let the record show appreciation for Shinobu and Dan.

We'll now have our public comment period, and let me begin with the ground rules. Please begin by identifying

yourself and your organization, and limit your comments to no more than two minutes. When the red light comes back on, that will signify the end of two minutes.

And as always, I would remind people that this isn't your only, or even your best, opportunity to provide input to the Commission. Please use the staff and also our web site as a place to lodge comments.

MR. ELLSWORTH: Thank you. Good afternoon. My name is Brian Ellsworth, and I'm speaking on behalf of myself as someone who has been involved in post-acute and long-term care for over 25 years, and had occasion to think a lot about risk adjustment and those issues, and looking very actively at the bundling issue right now.

Two comments. One, I want to pick up on what Herb Kuhn said about looking at some of the foundational issues, particularly in the SNF and the home health payment systems, and the whole issue of using therapy, amount of therapy to predict use of therapy. It's basically a tautology, and it creates incentives to use it. The more you can figure out and crack that nut and deal with it, the better the bundling outcome will be, as well as your work in the silos on there. It's just a huge conceptual limitation of both of those due

payment systems that really kind of evolved as a result of a shortcut and really a way that they didn't have any other way to predict. So I would encourage your work along those lines.

Secondly, with respect to the risk adjustment itself and the comorbidity of the looking, the examination of comorbidities, there's a real tendency in a lot of the research to kind of bring in one issue at a time. Say a person has a hip fracture. Then you look at okay, they have a hip fracture, and they have diabetes. What's the effect of that?

They have a hip fracture, and they have congestive heart failure. What's the effect of that?

Instead what you need to do is look at the cumulative burden of illness that that person has. Do they have a hip fracture and three other things wrong with them? Do they have a hip fracture and 10 other things wrong with them? You will get a different picture than you will get by looking at those additional issues one at a time.

And there's a variety of things out there, like the Nursing Severity Index, I think you can look at HCCs and some other stuff and come up with a way to kind of count

problems and conditions. Then from there, it gets a little bit tricky. It's not just as easy to kind of count because some things count more than others, but I would suggest that it's probably a total of about 30 issues -- late loss ADLs, cognitive impairment and some of the things you were talking about, primary diagnosis, and so on and so forth.

So I'd be glad to touch base with staff and provide some specific thoughts along those lines. Thank you.

MR. HACKBARTH: Okay, we are adjourned. Thank you.

[Whereupon, at 12:01 p.m., the meeting was adjourned.]