MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

Thursday, April 2, 2015
9:24 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[9:24 a.m.]

MR. HACKBARTH: So this is my last public meeting as MedPAC Chair, today and tomorrow, so if you'll indulge me, I just want to say a couple things at the outset.

So I've been on MedPAC for 15 years now, and during my tenure as Chairman, we've voted on over 300 recommendations. So with 17 Commissioners, that represents, you know, roughly 5,100 individual votes cast. Over that period, there only have been 32 no votes on those more than 300 recommendations, over 99 percent yes votes. And I take great pride in that. I think that's a remarkable degree of consensus for generations of Commissioners coming from very different backgrounds, different life experiences, different political perspectives. And to achieve that level of consensus I think is a great tribute to Commissioners, past and present, and to our wonderful staff, because I think the two key ingredients to getting to that level of consensus have been that Commissioners accept their responsibility to put the interests of the Medicare program and its beneficiaries first. They come to the task not as

representatives of a particular profession or a particular type of health care provider or a particular geographic region but, rather, they bring their experience and knowledge to the table and put the goals of the program first and foremost.

Our staff have contributed hugely to this through both the quality of their analysis and their responsiveness to the questions raised by Commissioners. And I can't overstate the importance of that in forging consensus on these issues.

And the issues haven't always been easy issues to deal with. I want to just quickly tick off a list of some of the things that we've made recommendations on in the last 15 years.

Of course, one of our basic responsibilities to the Congress is on annual updates and the various Medicare payment systems. I think we have applied a fairly rigorous, some would say demanding approach to that, resulting in updates that are certainly lower than many provider groups would have liked, using as our guidepost efficiency providers. And I think our work in this area has set the stage for Congress to arrive at update

recommendations that are lower than they might have otherwise, including in the Affordable Care Act, where they set lower statutory updates pretty much across the board. And they've done that again in the pending SGR legislation. Providers may not like that, but I take pride in our role in supporting Congress in that area.

We've made a variety of recommendations to improve the equity in Medicare's payment systems, and by their nature, these adjustments redistribute dollars, and there are winners and losers. Yet the analysis supporting the work has been strong, and some difficult changes have been made: severity adjustment for inpatient hospital services, improvements in RVU accuracy in the Physician Payment System, changes in how rural providers are paid, improved payment equity between rural providers and urban providers.

We've made recommendations on site-neutral payment. To this point, Congress has only adopted them at the margin, but those have been difficult, challenging issues I know for many Commissioners, and I'm proud of the work we've done in that area.

We made very important recommendations on GME

reform and Medicare's role in financing graduate medical education.

We've made recommendations on benefit restructuring that I'm hopeful still will find their way into legislation because I believe the current benefit structure, with all of its peculiarities, dating from 1965, really isn't in the interest of Medicare beneficiaries. I think, frankly, it's more in the interest of people who sell Medigap insurance than it is in the interest of Medicare beneficiaries.

Long ago, in fact, one of the very first recommendations we made after I became Chairman was to move towards financial neutrality in Medicare Advantage, namely, that we ought to pay the same amount for a beneficiary regardless of whether he or she was in traditional Medicare or enrolled in an MA plan. Congress took a big step in that direction in the Affordable Care Act.

We laid the groundwork for a lot of the Medicare payment reforms that are now under consideration -- some in law, like ACOs; others being tested in CMMI.

We were one of the early advocates of a public database on physician financial relationships, the so-

called Sunshine Act, which is part of law now.

We were one of the early advocates of a major federal investment in comparative effectiveness, which is now embodied in PCORI.

And last, but certainly not least, we were very early advocates of SGR repeal. Again, that was something we recommended in 2001 when it wasn't nearly as popular as it has become in recent years, and hopefully in the next couple weeks that will become law as well.

So to deal with difficult, complex issues like these and achieve the level of consensus that we have I think is a record that all of us should be proud of. I know I am.

And to those of you in the audience, there are a lot of familiar faces. Some of you I see sort of month after month after month and year after year after year. I know that doesn't signify that you necessarily agree with what you're seeing. In fact, maybe it means the opposite, that you're here because you don't agree with it. But I do welcome and I'm grateful for the interest that you've shown in MedPAC's work, so thank you for that.

So, with that, let's turn to our agenda--

[Standing ovation.]

MR. HACKBARTH: Thank you.

Can we go on now?

[Laughter.]

DR. MILLER: You're the Chairman.

MR. HACKBARTH: Right, for a little while longer.

Okay. So, Zach, are you going to lead the way on hospital short stay?

MR. GAUMER: Yes, sir, that's right.

MR. HACKBARTH: And, incidentally, I don't want anybody to feel any pressure about votes.

[Laughter.]

MR. HACKBARTH: But I do count.

Zach?

MR. GAUMER: Okay. Good morning. Today we'll discuss the five draft recommendations you've assembled concerning short hospital stays. Based on your discussion, the Chairman will initiate the voting process.

To review from the Commission's four previous discussions, the origins of this issue lie in both the complexity of the admissions process and the payment differences between similar inpatient and outpatient stays.

These factors led RACs to focus their audits on short inpatient stays, and in response, hospitals increased their use of outpatient observation.

CMS took action to resolve these issues by implementing the 2-midnight rule. The rule has been controversial, and its full implementation has been delayed repeatedly.

For beneficiaries served in outpatient observation, there is fairly broad concern that they are occasionally surprised to learn that they are in observation status. In addition, while liability is generally lower for beneficiaries served in observation status, these beneficiaries can be exposed to higher financial liability with regard to SNF coverage and self-administered drugs.

The five draft recommendations we will discuss are listed on the slide above. They have been slightly modified from what you've read in the mailing materials you received last week.

The first recommendation pertains to the RAC program, and the withdrawal of the 2-midnight rule has been incorporated in this recommendation.

The second recommendation concerns the hospital short-stay penalty concept.

The last three recommendations focus on improving beneficiary protections for those served in observation status.

The first recommendation we will consider today concerns specific changes to the RAC program. In its work this year, the Commission has identified three concerns about the program:

First, that it has significantly increased the administrative burden of hospitals;

Second, that the exception of losing payment when their claim denials are overturned -- excuse me. Second, with the exception of losing payment when their claim denials are overturns, RACs are not held accountable for their auditing determinations;

And, third, that hospitals are unable to rebill RAC-denied claims as outpatient claims due to the misalignment of the three-year RAC lookback period and the one-year hospital rebilling window.

As you will recall, at our last meeting Herb suggested we give consideration to crafting a

recommendation about removing CMS' 2-midnight rule. We have discussed this rule publicly on several occasions, and we have built this topic into the draft recommendation pertaining to the RAC program because the rule is a directive to auditors. Retaining the 2-midnight rule may be redundant in the context of our larger package of recommendations on this topic.

For a moment, let's review what the 2-midnight rule is. CMS established the 2-midnight rule for fiscal year 2014 to alleviate concerns about admission criteria, long observation stays, beneficiary liability, and hospitals' concerns about RAC audits. This rule instructs auditors to presume that stays longer than 2 midnights are appropriate for inpatient status and should be exempt from audit, with some exceptions. It also instructs them to presume stays shorter than 2 midnights are more appropriate for outpatient status and, therefore, are subject to audit. This rule does not directly alter Medicare admission criteria, but it will alter providers' admitting behavior.

Congress and CMS have placed RAC enforcement of the 2-midnight rule on hold several times since its implementation. The most recent hold expired this past

Tuesday, March 31st, but legislation to extent the hold is included in the active SGR legislation, H.R. 2.

The 2-midnight rule may have successfully achieved a few of the goals that it was designed to address. It alleviates a portion of the RAC-related administrative burden hospitals face, and it will reduce the use of long observation stays. In addition, some hospitals have been pleased with the fact that it essentially creates the time-based standard for inpatient services.

However, the 2-midnight rule raises a number of concerns. It largely exempts stays longer than 2 midnights from RAC oversight, and it provides hospitals with the incentive to increase the length of stays beyond 2 midnights in order to avoid RAC scrutiny. The lengthening of the stays may result in an increase in the use of short observation stays and, therefore, exacerbate concerns about SNF coverage eligibility. Overall, the incentive to increase the length of stays may act to eliminate 1-day inpatient stays entirely.

Stakeholders have also noted that the rule detracts from the current admissions criteria based on

physician judgment, increases burden on physicians to document admission, and causes significant shifting of cases between the inpatient and outpatient settings.

For these various reasons, the Commission is considering the complete rather than partial withdrawal of the 2-midnight rule.

Based on our evaluation of the RAC program and the 2-midnight rule, the Commission's four-part draft recommendation reads as follows:

The Secretary should direct Recovery Audit Contractors to focus reviews of short inpatient stays on hospitals with high rates of this type of stay; modify each RAC's contingency fees to be based, in part, on its claim denial overturn rate; ensure that the RAC lookback period is shorter than the Medicare rebilling period for short inpatient stays; and withdraw the 2-midnight rule.

We expect this recommendation will increase program spending because it will cause RACs to take a more cautious approach to auditing, resulting in fewer claim denials and a lower level of recoveries. It will also increase rebilling opportunities and allow hospitals to gain partial reimbursement for services that were otherwise

denied.

We do not expect this recommendation will adversely affect beneficiary access. However, the effect on beneficiary cost sharing may be mixed due to stays shifting between the inpatient and outpatient settings.

For hospitals providing a high rate of short inpatient stays, this recommendation will increase RAC scrutiny of short stays and administrative burden. However, for the remainder of hospitals this recommendation will either reduce or eliminate RAC scrutiny and the associated administrative burden. Also, we expect this recommendation will benefit hospitals financially because it will enable more rebilling of denied inpatient claims and reduce administrative costs associated with RAC record requests and physician documentation requirements.

Our evaluation of the RAC program has also led the Commission to consider the potential for a formula-based payment penalty on hospitals with excess levels of short inpatient stays to replace RAC reviews of these stays. Interest in this concept is derived from concern that the RAC program is administratively burdensome for hospitals and CMS, and oversight of hospitals could be made

more efficient.

Therefore, the Commission is recommending:

The Secretary should evaluate establishing a penalty for hospitals with excess rates of short inpatient stays to substitute, in whole or in part, for RAC review of short inpatient stays.

The penalty concept may reduce administrative burden on hospitals and CMS and make oversight more efficient. However, the Secretary will need to address several design elements in evaluating this concept, such as how to define short stays, identifying an appropriate penalty threshold and penalty amount, and risk-adjusting the measure to make it equitable for all hospitals.

Because this recommendation is for the Secretary to evaluate rather than implement this concept, we expect this recommendation will not increase Medicare program spending or adversely affect beneficiaries or providers. While we are asking the Secretary to evaluate this concept, we will also be conducting our own evaluation.

Stephanie will now discuss the Commission's beneficiary protection recommendations.

MS. CAMERON: Turning now to our draft

recommendations on beneficiary protections, you'll remember that beneficiaries with an outpatient observation stay who are then discharged to a skilled nursing facility without qualifying for Medicare's SNF benefit are at risk of substantial financial liability for their post-acute care. In addition, these beneficiaries are at risk of incurring out-of-pocket expenses for self-administered drugs, as these drugs are not covered by the outpatient payment system.

The Commission has considered recommendations with regard to revising the SNF 3-day prior hospitalization policy, beneficiary notification requirements, and beneficiary financial liability for self-administered drugs which I will review today in turn.

First, the 3-day prior inpatient hospitalization requirement for SNF coverage.

A small group of beneficiaries incur high out-of-pocket costs because their 3-day hospital stay did not include three full inpatient days, leaving them without SNF coverage. As you may recall, time spent receiving outpatient observation care does not count toward the 3-day requirement for SNF coverage.

In an attempt to find a balance between expanding SNF eligibility to include beneficiaries receiving observation care and preserving the SNF benefit as strictly a post-acute-care benefit, the draft recommendation reads:

The Congress should revise the skilled nursing facility three inpatient day hospital eligibility requirement to allow for up to two outpatient observation days to count towards meeting the criterion.

The Commission anticipates that this policy will increase program spending for the beneficiaries who will now qualify for SNF coverage. The overall impact of this policy on spending is dependent on the behavioral response of beneficiaries and providers. For example, a lower threshold for Medicare SNF coverage could provide a greater incentive for nursing facilities to send beneficiaries to the hospital in order to requalify for the SNF benefit.

The Commission anticipates that this policy will have a positive impact on the beneficiaries who are discharged to SNFs without Medicare SNF coverage currently. Beneficiaries such as these will see their out-of-pocket post-acute-care liability reduced dramatically. This recommendation would also increase Medicare use of and

payments to freestanding and hospital-based SNFs.

The Commission has discussed beneficiary uncertainty about the differences between inpatient status and outpatient observation care. Medicare currently does not require hospitals to notify beneficiaries of their outpatient observation status regardless of the time these beneficiaries spend in the hospital. Medicare beneficiaries and beneficiary advocates often cite this lack of notification as a source of confusion for beneficiary SNF eligibility and cost-sharing liability.

Several states have laws or are considering law that require hospitals to inform patients about their status in observation. Earlier this month, the House of Representatives passed legislation addressing this issue on the federal level in what is called the NOTICE Act.

I would be happy to discuss this further on question.

In the meantime, the draft recommendation to address beneficiary notification reads: "The Congress should require acute care hospitals to notify beneficiaries placed in outpatient observation status that their observation status may affect their financial liability for

skilled nursing facility care. The notice should be provided to patients in observation status for more than 24 hours and who are expected to need skilled nursing services. The notice should be timely, allowing patients to consult with their physicians and other health care professionals before discharge planning is complete."

When CBO evaluated the NOTICE Act, they determined that, as passed by the House of Representatives, the legislation would not have significant budgetary effects over the 2015 through 2025 period. We expect that hospitals will need to make administrative adjustments to accommodate this change and, thus, likely incur an administrative cost to implement this policy.

Lastly, we will discuss self-administered drugs in outpatient observation care.

Beneficiaries who receive outpatient observation services may be in the hospital for an extended period of time, for example, 24 hours or more, and require some of their oral medications that they would normally take at home. As you'll recall, oral drugs and certain other drugs that are considered usually self-administered are not covered by Medicare for hospital outpatients. The extent

to which beneficiaries are affected by this issue varies by hospital. Some hospitals reportedly do not charge beneficiaries for self-administered drugs. Other hospitals contend that they must charge beneficiaries for self-administered drugs because of laws prohibiting beneficiary inducements. These facilities may bill the beneficiary at full charges, which equals approximately $200, on average, which is substantially higher than the cost of providing the drug, which equals about $40, on average.

The draft recommendation to package self-administered drugs in the outpatient payment rate reads: "The Congress should package payment for self-administered drugs provided during outpatient observation on a budget neutral basis within the hospital outpatient prospective payment system."

Under this approach, the Secretary would increase outpatient payment rates for all beneficiaries receiving observation care to reflect coverage of self-administered drugs, while payment rates for other outpatient services under the OPPS would decrease slightly to offset it, resulting in no additional Medicare spending.

Overall, this option would also reduce

beneficiary liability for self-administered drugs. Beneficiaries receiving observation care would no longer be liable for non-covered self-administered drugs at full charges. In addition, this option would also make cost sharing for self-administered drugs uniform across beneficiaries and hospitals paid through the OPPS.

We expect that hospitals would experience a small decrease in revenues from no longer receiving full charges from beneficiaries. However, this policy may reduce hospital administrative burden associated with cost sharing collections and beneficiary complaints concerning self-administered drugs.

We have reached the end of our presentation today. For your reference, here's a quick summary of the draft recommendations we've discussed, and with that, I will turn it over to Glenn.

MR. HACKBARTH: Okay. Thank you, Zach and Stephanie.

So, we'll have two rounds, our usual clarifying questions, strictly defined, and then a second round where each Commissioner may, if he or she wishes, state their overall view on the package of recommendations before we

vote.

So, let's start with clarifying questions. Are there any clarifying questions from Commissioners? Jack.

DR. HOADLEY: I just wanted to clarify, I think it's in the text, but on the recommendation on the RAC, when we talk about the denial overhead rate as a basis, you say in the text that the Secretary should have latitude to define the rate. So, we're not setting any particular definition for the rate in our recommendation.

MR. GAUMER: That's correct. There is some, I think, debate generally in the policy community, in the weeds, anyway, about what rate should be used and how it should be defined. So, we're not being specific in the text about which rate should be used, and the Secretary should have some latitude.

DR. HOADLEY: And, then, a similar question on the rebilling thing. There obviously are different ways to define exactly what the time period should be and we're not taking any particular position. I know there's language in the text about principles on hospitals not being able to fully exhaust appeals and a clear window for rebilling.

MR. GAUMER: That's right. So, the

recommendation that we have up there is a principle-based recommendation and, you know, the Secretary should be able to define the right balance between appeal and rebilling and it's a complicated decision.

DR. HOADLEY: Great. Thank you.

MR. HACKBARTH: Clarifying questions. Bill.

MR. GRADISON: Thank you. In the mailing material on page 13, the text box refers to a list of changes that CMS announced with regard to the RACs, that CMS announced in December of last year. I just wonder what the status of this is. My impression is that that issue ended up in court in some manner or other, and could you just tell us the facts there, please.

MR. GAUMER: Yes. So, that issue did end up in court. Let me go back. CMS released a list of 18 different changes that they wanted to make to contracts going forward, and I believe that happened late in December. The first contract that got signed, there was a lawsuit, and it had to do with -- it had to do with the provision that said, after which point the hospitals will -- after which point in the appeal process the money would exchange hands again. And, that lawsuit, I believe, is

still in kind of an appeal process, and it's in limbo, I think is the way to leave that.

And, CMS has informed us that they have some leeway to begin to do these changes, these 18 changes incrementally as this occurs. And, so, some of these things are being implemented slowly with the RACs before the contracts are being -- the new contracts are being signed. And then the new round of contracts, they hope -- CMS hops to get these components, these 18 components, into the new contracts.

MR. GRADISON: Thank you.

MR. GAUMER: Okay.

MS. BUTO: Two clarifying questions. On the issue of the 2-midnight rule, there was an 0.2 percent reduction made to compensate for what CMS was projecting would be additional costs associated with it. Did we look at or address -- I'm trying to -- I was looking in the text, but couldn't find whether we addressed whether we think that should be restored, whether there ought to be any, you know, compensating calculation made there.

MR. GAUMER: So, there's not a broad discussion of the 0.2 in the text.

MS. BUTO: Mm-hmm.

MR. GAUMER: I think our general position has been that it should be restored if it was implemented with the 2-midnight rule. If the 2-midnight rule were to be withdrawn, the 0.2 should come back in --

MS. BUTO: Okay.

MR. GAUMER: -- and that's where we --

MS. BUTO: And then my second clarifying question is, the recommendation is for self-administered drugs to be folded into OPPS just for observation stays, or days, rather, observation days. Dave and I were talking about stays, and stays is an inpatient concept. What would the additional cost be of including self-administered drugs for all OPPS services? Do we have a number on that?

MS. CAMERON: We do not have a number on including the cost for all OPPS services. We had done some preliminary look at some of the ER visits and surgery, and if we added those in, we expect, based on our calculations, that to cost about $100 million a year. But, that hasn't been something we've thought through in terms of the implementation or the appropriateness for all of ER or all of surgery to be included.

MS. BUTO: Okay. So, $100 million on top of the estimated $50 million that we think goes with observation, or just a total of $100 million?

MS. CAMERON: A total of 100.

MS. BUTO: Okay. Great. Thank you.

MS. CAMERON: So, it just about doubles it.

DR. SAMITT: Great work yet again on this chapter.

I think this is probably a question for Stephanie. On Slide 14, you talk about the administrative burden on providers of this recommendation. I was wondering if you had some discussion and dialogue about whether you thought that this recommendation would increase in any way substantively length of stay. So, if beneficiaries are now made aware of the implications of the SNP eligibility rule, would it then lead to longer stays, potentially?

MS. CAMERON: We had -- in thinking about this, we wanted to ensure that this remained a discussion with beneficiaries and their physicians or other health care professionals. It's unclear to us how that will play out and what the ultimate behavior will be. There could be a

situation where a beneficiary may have been recommended to be discharged to a skilled nursing facility, but because of a subsequent conversation, they decide that maybe home health is a better option. In that case, I don't think we would expect length of stay to be increased. However, there could be circumstances where that may happen.

DR. SAMITT: Thank you.

MR. KUHN: So, a quick question about the appeals backlogs and the announcement last year of CMS to enter into a settlement agreement with hospitals at 68 cents on the dollar if they were to drop their appeals. That process is now closed, and I know we referenced it in the reading material, but do we know what the take-up rate and how much that decreased the backlog?

MR. GAUMER: Let me just ask a clarifying question to your question.

MR. KUHN: Yes.

[Laughter.]

MR. GAUMER: The backlog, in terms of how much the 68 percent settlement has resolved the 800,000 appeals? Is that what you're asking?

MR. KUHN: That's correct. Yes.

MR. GAUMER: Okay. We don't have a sense yet for the result of that settlement. Just the other day, the three of us were talking about this. CMS's most recent information on this came out in March, I believe, and what they've said is that the process of filing for the settlement, in other words, the hospitals initiating that they would like to take advantage of the 68 percent deal they can get, that has closed and, I think in October, hospitals had to let everyone know -- let CMS know that they were interested, and as a result, CMS is supposed to release a report on what occurred fairly soon. But, we haven't seen anything yet. So, they're probably ironing out how this all works.

MR. HACKBARTH: Any more clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Let's move, then, to round two. As I said, this is an opportunity for Commissioners to state their views about the overall package of recommendations. I don't think we need to go through them one by one. Just treat it as a package. And, as I say, don't feel obliged that everybody's got to talk, but this is your chance if you want to go on record with a view of

the overall package.

Cori, and then Herb, and we'll come around this way.

MS. UCCELLO: Well, I support the entire package of recommendations, but I just want to call out my particular appreciation for the notice recommendation wording that, I think, changed a little from last time to specify more the timing of that notice, and I think it's really important that this be done before people are walking out the door, or being wheeled out the door. So, I think -- so, I just really appreciate this new wording, so thank you.

MR. KUHN: I, too, want to say that I support the package of recommendations. There's a lot of recommendations here, as we all know, and we've been through a lot of material here. But, it's just a challenge to think that clinical judgment, and physicians have been admitting people to hospitals in the Medicare program since 1965, and who would think that we're here in 2015 still struggling with what that admission criteria kind of looks like, to a degree. So, the fact that we're trying to get some clarity here and looking at a fairly complex set of

recommendations, hopefully, we'll give some predictability and stability for folks as they think this through.

But, also, I think some of the other recommendations here dealing with the rebilling issue, the 2-midnight rule, the three-day prior hospitalization with SNF benefits are all improvements to the program.

So, overall, I think it's a terrific package, and I want to compliment the staff for bearing with us, because we have been back and forth on this issue so much over many sessions, and I think the write-up of the material is extraordinarily well done.

DR. CHRISTIANSON: Yeah, I also support the package as a whole, but I want to -- I mean, a lot of the discussion around this has been around hospital payments and issues with respect to hospital payments, but I am particularly pleased that the recommendations regarding the beneficiaries became part of this package. I thank the staff for working on that.

DR. CROSSON: Thank you. I support the five recommendations. I think it's a good package.

I'd just like to make one comment on the 2-midnight rule. I think, based on our conversations on this

issue, a lot of people in the health care industry are going to be happy to see in the recommendation that we withdraw the 2-midnight rule. On the other hand, it does provide a safe harbor and a clear line for hospitals in what is a very complex clinical judgment arena, and I think it's important to emphasize, as we will, that that recommendation does not actually stand alone. It is, in fact, linked to the other recommendations with respect to reform of the RAC process. And, to the extent that people -- and there will be some who are concerned about this recommendation -- they need to understand that our intention has been that this withdrawal would be in the context of overall reform of the RAC process.

DR. NAYLOR: I also support the recommendations. I want to reinforce Jon's comments. I think that the collection of recommendations just places the centrality of the beneficiary in this program front and center, with self-administered drugs, with attention to what is a SNF stay, and with the efforts to really make sure that beneficiaries understand their rights in this program. So, I really think that this reinforces your earlier -- your introductory comments about everybody stepping out of

themselves and really placing the program and the recipients front and center.

DR. HALL: I, too, wanted to commend you on not only this particular material, but all the material that's been prepared on this issue. I think it's the best explanation available anywhere. This is a very, very confusing literature.

For example, we talk about the 2-midnight rule creating a safe harbor. It's a safe harbor for administrative issues. It's not a safe harbor for patients. And, if we look at our Medicare recipients as our primary responsibility, there are many instances where strict adherence to the 2-midnight rule could adversely affect patient care. Some of these individuals who are put in observation status are considered sort of not very sick, when, in point of fact, they often have very serious illnesses.

It also assumes that health care providers are superior and infallible diagnosticians, and that's not a true statement. One thing one learns over time in clinical medicine is to be very humble about decision making.

So, any kind of sort of unofficial restraints,

artificial restraints on getting the right care at the right time can really harm people. And, so, I think we would do well to eliminate the 2-midnight rule. But, as everyone else, I am sure, will be saying, it has to be in conjunction with some of the important reforms we've put into the RAC process. And, I think we're really -- this is a very, very exciting initiative that we're embarking on now. I'm in favor of these recommendations.

MR. GRADISON: My support for eliminating the 2-midnight rule goes to the desire to put nothing in the way of shortening lengths of stay, which have been shortened dramatically over the years. We have no way of knowing what changes may come about in the future that might lengthen or shorten stays, but I hate to have something on the books which would stand in the way of having a very intense one-day and then sending people on to some kind of post-acute care rather than staying longer.

DR. NERENZ: Yeah. I'm happy to support the recommendations, and I appreciate the great work on what's really a complex issue, in part because it's not just one problem. It's at least two, maybe more related problems. And, the things that we've talked about here, I think, are

things that can be achieved in relatively short term and sort of that's the scope of the discussion.

I think once we put that behind us, going forward, I'm still going to be concerned about, from the beneficiary point of view, these really long outpatient so-called stays. That's not the right word. And, I think we ought to continue for ways to avoid what we hear from our physician colleagues is an essentially arbitrary distinction for people who are under a hospital roof, they're in a bed, they're surrounded by nurses, they're having things done to them, but yet we still maintain this dichotomy. So, I'm perfectly happy with what we're doing here, but I think we still have perhaps a little work to do going forward.

MS. BUTO: I want to just say this is incredible work on the Staff's part because this is probably the most complex issue I can remember dealing with, and I've been dealing with Medicare issues for a long time. So I want to just commend you for the work.

I fully support all the recommendations. I want to just express worry about the formula-based penalty, and it goes a little bit to what Bill Gradison was just saying

about standing in the way of trying to shorten unnecessary length of stay.

I worry on two fronts. One is that an across-the-board penalty where if its threshold is sent for hospitals having one-day stays, disregards whether or not those stays are medically necessary, and once you get into trying to sort of slice and dice and only look at the not medically necessary ones, it gets into a very convoluted process. So if you keep it clean and it's across the board, you're going to catch medically necessary one-day stays, and hospitals will face a penalty for those as well.

And then the other point that Bill was making about just -- I fear it is a little bit like the 2-midnight rule. You could sort of be setting up a situation where two inpatient stays creates a safe harbor against this penalty.

So I just register that. I realize what we're recommending is an evaluation, but I just want to say that I think there are some potential pitfalls there.

Lastly, the only other thing I would love to see us at least call out is the possibility of folding in self-administered drugs for all OPPS into the rates, if it's

$100 million or so. The idea that beneficiaries are going to be charged full charges for these drugs in everything except observation stays or days, I think would be -- the burden is going to remain there, and I think it's kind of unnecessary. So I'd like to see both of those changes or at least call out the possibility of those issues.

DR. COOMBS: Thank you very much for an excellent chapter, and I really appreciate the whole process of this discussion on appeals.

I support the recommendation. I just want to echo just my concern again about the penalty and the recommendation regarding evaluate. I think that one of the things that we have talked about is just this whole notion of looking at different critical access hospitals and also the DSH hospitals.

One of the experiences -- I was discussing with one of the hospital executives, and one of the experiences they talked about was the whole notion of the probe and educate and what they have experienced with the 2-midnight rule and their denials. And they got into a deep discussion when they did their case reviews about, okay, why was this considered, why was this denied. When they

asked about clinical criteria, they were fraught with very disappointing answers. That piece of it, the probe and educate, is not internally consistent, I think, from one region to the other.

Hopefully, with the RAC reform, there is also this discussion about what's the criteria for denial that goes beyond the 2-midnight rule. I strongly agree with the withdrawal of the 2-midnight rule, but the whole piece with probe and educate, I think is something else that going forward the RAC will have to deal with as well.

Thank you.

DR. HOADLEY: Yeah. I want to join others in thanking the staff. Teaching us on a very difficult issue how to think about this and answering a lot of sometimes naive questions has shown a lot of great work from the staff and also join others in support of these recommendations, and I think it's a great example of the sort of consensus process. We might not all have written every one of them exactly the way they came out, but we're all seemingly very comfortable with the package as a whole. I also join Jon, Mary, and some others in really appreciating that we have addressed some of the particular

beneficiary issues that came up in this, and I think that's a really helpful thing.

MR. HACKBARTH: Any others?

Oh, Warner.

MR. THOMAS: Just a couple of comments. Number one, as we all understand, this is a very complex issue, and patients are all different, quite frankly.

I suppose the recommendations. I just want to make a few comments, not to change recommendations, but if they could be in the verbiage as this is put forth.

First of all, the issue around the RAC reform, I think is extremely important in this whole rule. I know that in the chapter, it talked about a 1 percent reduction for RACs that see high overturn rates. I would just encourage us to make sure it is a material impact to the RACs because depending upon the rates you look at, between 65 to mid-70 or high 70s of appeals, essentially overturn the RAC review. So that is, I think, a big issue for providers and certainly puts the beneficiary in the middle as that whole process is being considered.

I know in the recommendation, it talks about making sure the period is long enough to allow the rebuild.

I just think it's important that we take into consideration the appeal time frame as we go through that. I know that there's a one-year limitation. I'm not sure in the recommendation if that would be modified to make sure that a provider has enough time to go through the complete appeal process and then be able to rebuild. I would just make sure that that's something we have an opportunity to comment on.

I would agree with Kathy on the formulaic approach. I would just encourage us to be careful if we go down that road. Given the nature of this, I think that can be a challenge.

Then, finally -- and I had asked this clarifying question earlier about the rate of one-day stays. If we're going to look at percentages, which I think is important, because otherwise you could potentially penalize large organizations that see lots of Medicare patients. On the flip side of that, if you have a very small provider that has very few cases, a percentage could be a challenge as well. So I think we just need to balance those two and maybe look at some sort of threshold of number of cases and then look at percentage. I just would make that small

comment.

Then, lastly, just in the comment of -- I know in the 2-midnight rule, we talk about the issue that there is a safe harbor after a 48-hour period, going to David's point. I mean, these patients are inpatients. I just think if there could be a comment about -- or some guidance to RACs about how they are going to look at these patients, if they are an observation in for a couple of days, I just think that's an important component of the 48-hour rule or the 2-midnight rule. I agree we should revoke that, and I support the recommendation. I just think there ought to be a comment that is made in the verbiage.

But with those comments, I certainly approve the recommendations and think it's been great work. Thank you.

DR. REDBERG: First, I want to add my thanks to the Staff for an excellent chapter on very complex issues, and I support all of the recommendations.

Just building on what others have said in terms of the appropriateness, I think in the future, it's important to also look at the appropriateness because a lot of these inpatient observation stays happen to be in the cardiac area, like chest pain, cardiac arrhythmia, and the

question is whether they should be held at all or whether these really should be outpatient, because a lot of data shows in the low-risk chest pain, which mostly these are people with funny kind of symptoms, normal EKGs, negative enzymes, 90 percent of them don't even have cardiac disease and have a very low event rate. So overall, the question to me isn't so much observation or inpatient, but should they be held at all, or should they just be more appropriately kept in the outpatient and sent home to follow up with primary care doctors, which we hope are easily accessible?

But I support the current recommendations at this time.

MR. HACKBARTH: Any other Commissioner comments?

[No response.]

MR. HACKBARTH: This goes to your point, Rita. All of this is an artifact of Medicare-siloed payment systems, and in particular, having the inpatient system with its large and high-priced bundle lodged alongside an outpatient system, it isn't as bundled as much and has lower dollar values, and that creates the potential for an incentive to inappropriately hospitalize patients.

I think there is a broad consensus in the Commission that we all long for the day where we're focused less on how we manage the siloes and the problems that the siloes create and we have payment systems where there are better incentives for high-quality care for Medicare beneficiaries done in the most efficient way possible with the appropriate resource use.

We have a ways to get there, but I trust that you folks, once I'm gone, will finish the work very, very quickly. Yes, six months.

Okay. So we are ready to vote now. Draft Recommendation No. 1 is up on the screen. All in favor of Recommendation 1, please raise your hand.

[Show of hands.]

MR. HACKBARTH: Opposed?

[No response.]

MR. HACKBARTH: Abstentions?

[No response.]

MR. HACKBARTH: Okay. No. 2. All in favor of Recommendation 2, please raise your hand.

[Show of hands.]

MR. HACKBARTH: Opposed?

[No response.]

MR. HACKBARTH: Abstentions?

[No response.]

MR. HACKBARTH: Okay. No. 3. All in favor of 3?

[Show of hands.]

MR. HACKBARTH: Opposed?

[No response.]

MR. HACKBARTH: Abstentions?

[No response.]

MR. HACKBARTH: Four? All opposed to four --

[Laughter.]

MR. HACKBARTH: All in favor of Recommendation 4?

[Show of hands.]

MR. HACKBARTH: Opposed?

[No response.]

MR. HACKBARTH: Abstentions?

[No response.]

MR. HACKBARTH: And No. 5. All in favor of No. 5?

[Show of hands.]

MR. HACKBARTH: Opposed?

[No response.]

MR. HACKBARTH: Abstentions?

[No response.]

DR. SAMITT: So, Glenn, does that count at 85 additional votes to your tally?

MR. HACKBARTH: It does. It does.

[Laughter.]

DR. SAMITT: Or just 17?

MR. HACKBARTH: I have a calculator set up to do a new percentage rating.

Okay. Thank you, Zach and Stephanie and Kim and everybody who has contributed to this work on the staff. Very well done.

[Pause.]

MR. HACKBARTH: Okay. Polypharmacy is up next. Welcome home again, Joan. Good to see you. Shinobu, whenever you're ready.

MS. SUZUKI: Good morning. Today Joan and I are here to talk about potentially inappropriate use of opioids -- a topic we discussed last fall, and the related but broader polypharmacy issues that affect the quality of services provided under the Part D program. We went through a lot of clinical literature, but neither of us

have clinical expertise, and we are hoping for inputs from Commissioners, particularly from the clinicians. We plan to include this material in our June report to the Congress.

Here's the roadmap.

First, I'll provide a quick summary of the patterns of opioid use in Part D. It reflects more recent data, but the patterns are similar to the data presented to you last October. I'll also go over the concerns raised by the patterns we see in Part D. Next, Joan will go over broader polypharmacy concerns for the program. We'll conclude the presentation with both clinical and policy approaches that could be taken to address polypharmacy and potential overuse of opioids.

In October, we presented to you data on opioid use among Part D enrollees in 2011. The patterns we observed for 2012 were pretty much the same. Here's a quick snapshot of some of the key findings.

About 36 percent of Part D enrollees filled at least one prescription for opioids.

Use of opioids varied widely across states, with higher prevalence of opioid use in many Southern states.

Most opioid use was not for beneficiaries in hospice or beneficiaries who had been diagnosed with cancer, but use of opioids for other types of pain can be clinically appropriate.

Some conditions were more prevalent among beneficiaries who had opioid prescriptions compared to those who didn't. For example, we found a higher prevalence of conditions such as osteoporosis, bipolar disorder, and depression among those who used opioids.

About 10.7 million beneficiaries with no hospice stays or cancer diagnosis used opioids in 2012. Compared to beneficiaries who did not use opioids, these beneficiaries were more likely to be disabled under 65 and receive the low-income subsidy.

Some beneficiaries used a lot of opioids. About 500,000 beneficiaries with spending (for opioids) in the top 5 percent accounted for $1.9 billion in gross spending, or about 70 percent of the total amount spent on opioids in 2012.

Those beneficiaries filled, on average, 23 prescriptions at a cost of over $3500. Sixty-five percent of the beneficiaries in the top 5 percent were under-65

disabled beneficiaries receiving the low-income subsidy.

Those in the top 5 percent were more likely to have obtained opioid prescriptions from four or more prescribers and were more likely to have filled those prescriptions at three or more pharmacies.

These patterns of opioid use raise both clinical and program integrity concerns.

First, there is a real concern about effects on beneficiaries' health. Opioid use is often associated with polypharmacy in the elderly population. In 2012, beneficiaries who used opioids filled an average of 52 prescriptions per year from about 10 different drug classes.

Second, opioids have addictive properties with high risk for abuse and are most often connected to unintentional overdose. A recent study by AHRQ showed inpatient stays related to opioid overuse by Medicare beneficiaries rising by 80 percent between 1999 and 2012.

Finally, findings from government reports suggest that some of the opioid prescriptions filled under the Part D program may not be clinically indicated and potentially fraudulent, increasing program costs without providing

health benefits.

The issue of polypharmacy is not limited to the use of opioids. Now Joan will discuss broader polypharmacy concerns for the Medicare population.

DR. SOKOLOVSKY: Elderly Medicare beneficiaries with multiple chronic conditions frequently take many drugs. More than one-third of beneficiaries fill more than six prescriptions each month. Although there is no consensus definition of polypharmacy, researchers generally call it polypharmacy when a person takes six or more drugs concurrently. Alternatively, polypharmacy exists when a patient is prescribed more drugs than is clinically warranted or when all drugs are clinically appropriate but there are too many for a patient to manage or ingest safely.

For the past few years, Commissioners, as well as many other researchers, have been studying the question of whether adherence to medications reduces the use of medical services and medical spending. Our results were mixed. But as you've seen, many beneficiaries are taking a lot of medicines. So this year we wanted to start looking at the effect of a lot of drugs or polypharmacy on the use of

medical services. Somewhat to our surprise, we found little connection between the studies of adherence and those about polypharmacy.

The literature on medication adherence is quite different although both that and polypharmacy are concerned with patients taking appropriate drugs as prescribed. Researchers ask different questions, use different methodologies, and rarely cite studies from the other body of work.

Studies of adherence typically use administrative data with large data sets. They measure adherence in terms of possession of study medications. And they measure outcomes in terms of use of medical services and medical spending.

Polypharmacy studies require medical records and sometimes patient interviews. Since data collection is labor intensive here, sample sizes are usually smaller. Researchers also focus on adherence, but they define it much more broadly. Adherence means taking drugs as prescribed, not continuing to take drugs against doctors' orders or despite adverse events, taking the correct dosage, not sharing other people's medicine. And the

research is less focused on cost effects. Outcome measures tend to be adverse drug events, ED visits, or hospitalizations.

Although it may seem contradictory, polypharmacy is associated with nonadherence to appropriate drug therapy. Patients, especially older patients, often have difficulty managing complicated drug regimens, e.g., taking some drugs in the morning, some before bed, some with food, some without.

It is especially difficult when patients transfer from one site of care to another, like going from a hospital to home. They may not understand their physician's instructions. Some medications may be added, others stopped. And patients also may not tell their provider about over-the-counter drugs and dietary supplements that can interact with many other medications. They may also find the total cost of the drugs too expensive and stop some without telling their physician. Patients also may be unwilling to stop some drugs even when recommended by their physicians, for example, sedatives and sleeping pills.

Although adverse drug events are not necessarily

linked to polypharmacy, the association between the number of drugs a person is taking and adverse drug events is consistent across multiple studies using different data, sites of care, and research designs. It is a statistically significant predictor of hospitalization, nursing home placement, decreased mobility, cognitive decline, and death. It's frequently the only factor that is statistically significant in many of these studies.

A study of ambulatory care, for example, found that the number of adverse drug events per patient increased by 10 percent for each additional drug.

One study estimated that over 4.3 million health care visits were associated with adverse drug events, as well as 10 percent of all emergency department visits.

There are a number of mechanisms through which polypharmacy can lead to adverse drug events. One of them is therapeutic competition, which occurs when the treatment for one condition worsens another concurrent condition. For example, some medications used to treat heart failure can exacerbate urinary incontinence. More medications may result if a physician prescribes a drug to treat the incontinence rather than changing the heart failure

medication, leading to a prescribing cascade and more potential drug interactions.

Secondly, therapeutic duplication is defined as the use of multiple medications from the same therapeutic class at the same time. It can occur when a physician replaces one drug with another but the patient does not discontinue the first drug. This often can occur when a patient is using multiple pharmacies. One common example is NSAIDS, painkillers which can result in gastrointestinal distress including ulcers and bloody stools.

Finally, toxic combinations where the interaction between two drugs leads to serious complications. An example here is warfarin, a blood thinner, and simvastatin, a cholesterol-lowering drug, which together increase the risk of bleeding.

Some of the literature discusses how clinicians can reduce polypharmacy. Most frequently, they advise reducing the number of medications prescribed. Secondly, simplifying the drug regimen, for example, how and when the drugs are taken. Other suggestions are to limit the number of prescribers, avoid treating adverse drug events with more drugs if at all possible. Finally, patient and

provider education is necessary to ensure that patients understand the purpose of the drugs they are taking, how they should take them, and why it's important to only take them as directed.

Now Shinobu is going to list some policy options designed to address opioid overuse and other polypharmacy issues.

MS. SUZUKI: Part D provides limited incentives and tools for plans to address clinically inappropriate use of drugs, such as overuse of opioids and polypharmacy. Policies to address these issues must balance access to needed medications with prevention of inappropriate uses.

For opioids, there has been a lot of discussion around lock-ins. But before we discuss lock-ins, I wanted to draw your attention to another tool that has been used in Part D.

CMS has been encouraging plans to use point-of-service edits, such as limits on quantity, for beneficiaries with opioid use above a certain threshold.

There seems to be some reluctance among plan sponsors for this policy. One reason may be that there is no FDA-approved maximum dosage limit, and some plans have

expressed concerns because of this. Another reason may be because POS edit alone is unlikely to resolve all cases. Determining clinical appropriateness requires communications with prescribers, which can be time-consuming and may be particularly difficult for stand-alone PDPs because they don't have a contractual relationship with prescribers.

These kinds of issues may be behind the recent interest on the Hill and among plan sponsors for the lock-in policy. The idea is to prevent doctor or pharmacy shopping, which are often associated with overuse and abuse of opioids. They are already being used by state Medicaid programs and by some commercial insurance.

While the use of lock-ins may allow for an easier tracking of opioid prescriptions, identifying a potential overuse would still have to rely on some safety threshold, such as an MED limit, or morphine equivalent dose limit. In addition, determining the clinical appropriateness would require prescriber involvement, just as in the case of POS edits.

Finally, lock-ins may not work for LIS beneficiaries because they can change plans month to month.

Some have raised concerns about access. These policies could be combined with an allowance for temporary supplies while the case is being reviewed.

For broader polypharmacy and inappropriate use issues, we may want to consider ways to provide a stronger incentive to improve the quality of pharmaceutical service. For example, a performance measure could be added that is based on prevalence of inappropriate or appropriate use of drugs by their enrollees. That could be tied to payments.

Constructing an appropriate measure and determining the appropriate cutoffs would likely be a challenge. And such policy would need to be combined with more flexibility for plans to manage drug use.

Some in the commercial sector have reported success using medication synchronization. By dispensing all medications on the same day, pharmacists may be able to identify possible polypharmacy risks more easily and improve adherence to appropriate medications. It may also mean fewer trips to the pharmacy for the beneficiaries.

Finally, there has been some activity around provider and pharmacy profiling at CMS' Center for Program Integrity. We could look into this and see if more could

be done in that area.

So, to summarize, the patterns of opioid use by Part D enrollees raise both clinical and program integrity concerns. Goals of improving medication adherence for this population must be balanced against the risk of polypharmacy.

Policy options to prevent opioid overuse may be applicable to broader polypharmacy issues and issues related to inappropriate medication use. And, finally, potential policy changes would need to provide plans with appropriate incentives and tools.

And, with that, I'll turn it over to Glenn.

MR. HACKBARTH: Thank you, Shinobu and Joan.

So we will now have Round 1 clarifying questions, beginning with Warner.

MR. THOMAS: Did we or has there been any information looked at for the beneficiaries that are the high utilizers of opioids, other kind of underlying medical conditions or the medical costs of those beneficiaries in total?

MS. SUZUKI: We've looked at conditions. There were some that were more prevalent in those populations

than others. We have not looked into the medical spending side to see what that looks like, but the top 5 percent are disabled, under-65 beneficiaries -- or two-thirds of them are. That likely means higher spending than average.

MR. THOMAS: So two-thirds of the users are under 65 and disabled. Is that correct?

MS. SUZUKI: Two-thirds of the high users are under-65 disabled beneficiaries.

MR. THOMAS: Because, I mean, you would likely think that there's other underlying issues. I think we're targeting the pharmacy issue, but it's probably a much broader clinical issue, frankly.

MR. HACKBARTH: We'll go around this way.

MS. BUTO: This is somewhat related to Warner's question. A lot of this work is obviously focused on Part D plans, right? And yet how easy is it for Part D plans to track adverse drug events? Because they show up in emergency rooms and other providers, how much of that gets collected back? Isn't that an area of vulnerability here in terms of really being able to track polypharmacy and some of the events that come out of it? And I think it just -- you know, Warner's point about the underlying

conditions is very much related to that.

DR. SOKOLOVSKY: It is a problem if it's a stand-alone drug plan, especially if they have no way of tracking that. And even those who are tracking it, sometimes it's still subjective.

DR. NERENZ: I wonder if you could go to Slide 5, please, first bullet point. If you can just clarify for us a little bit what you mean here, what you want us to be thinking about here in two specific ways. The term "polypharmacy," as you pointed out, has two or three very different meanings and concepts, and I'm not sure here which one of those we're supposed to be thinking about. And also "associated with" can mean either just pure empirical correlation, or it could mean cause and effect, either one way or the other, or both caused by some third thing.

So what do you want us to be thinking about here?

DR. SOKOLOVSKY: We both have to answer this question. I think where Shinobu is using really large data sets, it really here means taking a lot of medicine. That's the only one that could be incorporated in that kind of a thing. But in terms of what you want, David, to be

thinking about, that's up to you.

MS. SUZUKI: Well, there are a couple policy options that we sort of showed at the end of the presentation, and opioid use, you know, could be dealt with with lock-in or other policy options.

DR. NERENZ: I don't even want to go there. I just want to know -- this really is purely clarifying.

MS. SUZUKI: Oh, okay.

DR. NERENZ: I think when you said this, you said people who use opioids fill, what, 52 prescriptions? So how does that compare to people who don't use opioids? I am just trying to understand this phrase associated with what -- why do you want me to -- what does that mean?

MS. SUZUKI: Well, one of the things we are finding in the literature is that opioid itself interacts with other drugs, so having 52 prescriptions from 10 different classes of drugs -- and some of them, we listed in the mailing material -- they could interact with each or that we were displaying that there could be polypharmacy, a lot of polypharmacy issues occurring in this population who are using a lot of opioid medications.

DR. NERENZ: [Speaking off microphone.]

MS. SUZUKI: Okay.

DR. MILLER: Well, I, too, would have struggled answering without thinking of policy, and I know, David, you were very clear to take that off the table for them. But I'm going to redefine the question.

I struggle trying to think through how we would answer your question, which I do whenever these guys are on point. I mean, the way I'm kind of thinking about this whole discussion is there is a lot of noise in the environment around polypharmacy and even more intense focus on opioid use and the concerns about the negative effects of those two things.

The way I'm thinking about our conversation here, it's harder for me, even though I think it's very insightful to sort of lay out the literature between adherence and polypharmacy and how they kind of, in some ways, don't talk to each other -- it's harder for me to think about polypharmacy because I think it's still harder to define and more complex to focus on the problem.

But opioid use, I think even in isolation and in connection with other drugs, I think for myself, speaking only for myself, that strikes me as a bit of a brighter

line. So the way I think about this conversation is, as a tool to think about how you manage drug use, should we look at opioid and think about policies that might make sense in that context? Next sentence. Maybe that will lead us close to something that on the broader issue of polypharmacy, we pursue down the line.

So the way I see it in the lineup is opioid sort of first in line and are there steps we would take there to look at that issue and perhaps address it from a policy perspective and then learn from that to go to polypharmacy.

But I'm not sure that's still your question. Your question seemed very narrow about association, and I'm not sure how I would have answered.

DR. SOKOLOVSKY: Can I try again?

DR. MILLER: My point was to give you some time.

[Laughter.]

DR. SOKOLOVSKY: And I appreciate it.

DR. NERENZ: Nicely done.

DR. SOKOLOVSKY: If you think about the different kinds of polypharmacy that were discussed in the paper, opioid is really a very good example of all of them and taking it. First of all, of all drug classes, it's the one

most associated with unintentional overdose, and part of that is therapeutic duplication. There are lots of different kinds of opioids, and people are getting prescriptions for different ones and taking them at the same time.

Another issue is a therapeutic competition because they're not just taking opioids. They're taking a whole range of other painkillers, and some of them have additive effects.

So it's kind of many of the worst features of polypharmacy you see with opioids, and the more drugs you're taking, the more likely that is to happen.

DR. NERENZ: That's okay. What you just said at the end is helpful because I wasn't picking up that particular implication from that phrase.

MR. GRADISON: In the material you sent out in advance, on page 17, you refer to CMS creating the overutilization monitoring system. How long has that been -- I realize it's too early from what you say in here to get much in the way of useful information, but how long has that been underway, about?

MS. SUZUKI: I believe it's been used since 2013.

MR. GRADISON: And do you have any guesstimate in terms of how long it would be before we could gain useful information? Because that's really right on point.

MS. SUZUKI: In the past couple of years, CMS has been providing their progress report, so to speak, on opioid utilization, and last time, they presented data from 2011 or '12 back in the fall. They may come back and revisit this issue and present more data on this.

MR. GRADISON: Okay. Not sure when.

I wanted to ask your thoughts with regard to some of these state registries that have been created. While our focus is on Medicare beneficiaries, the more I think about this issue, the more I think that we've got to take a look at the broader issue for a whole lot of reasons, people aging into Medicare and in particular the younger people who are disabled. Could you as a general matter share with us your thoughts with regard to these registries? And then I've got a few very specific questions related to those that I'll ask in a moment.

MS. SUZUKI: HHS has recently issued a brief talking about the PDMPs and the Prescription Drug Monitoring Program that states run and how some states have

had some success with using the use of opioid. It is difficult to measure how effective PDMPs are generally because each state has different rules and structure, but I think run in the right way, you could get some reduction or change in behavior by prescribers and beneficiaries.

MR. GRADISON: Are there any restrictions under the Medicare rules that would prevent participation in these state programs and in sharing this information with regard to specific patients?

MS. SUZUKI: My understanding is it's a state-by-state program. States determine who can access the information.

MR. GRADISON: No. I'm talking about what information they would require to be sent to the state. Are Medicare beneficiaries, that is, the prescriptions for opioids for them treated just like prescriptions for opioids for non-Medicare beneficiaries --

MS. SUZUKI: I believe so.

MR. GRADISON: -- under these state programs?

MS. SUZUKI: Yes. I think so. It is usually the states may require all prescribers who prescribe controlled substances to report all medications they prescribe, for

example, in states' different rules, but it doesn't distinguish between what coverage that person has.

MR. GRADISON: All right. Well, in that connection, how about VA? I thought I read somewhere that VA was not sharing that information, and I think it may be relevant because that would perhaps be an important component of the disabled under the Medicare program. Perhaps you could enlighten us on that at another time.

Finally, with regard to admission to SNFs, it's been a while, but at one point, I did some work with consulting pharmacies, and I was struck by the data, which may be out of date, but as I recall, it was that it went like that. On admission to a SNF, there was requirement to assess the utilization of drugs for each admission, and that on the average, each person coming into the SNFs was on nine or ten medications, order of magnitude, and that on the average, they were reduced by two on admissions to duplications and other factors.

The question is, have you talked to the consulting pharmacist folks to see the extent to which what their observations are with regard to opioid use that they may be able to measure very specifically at the point of

admission to a SNF for Medicare beneficiaries?

Thank you.

DR. HALL: Two very important and somewhat related topics to polypharmacy and opioid abuse. I'm just curious, as a clarifying question, why you chose only opioids as kind of the single drug class to concentrate on in the setting of polypharmacy in a Medicare population.

DR. MILLER: Want me to do this, apparently? Again, I don't know if this answer is really satisfactory . There is a lot of attention on this out in the environment right now, both in the states and at the federal level. Our sense in traveling through the world and the people that we talk to, there's been a lot of focus on this, and so I think that's part of the reason we've kind of started there -- and again, I didn't do a very good job -- and see ourselves working out from that point, but a lot attention right now.

DR. HALL: So the only reason I bring it up is they are both very important topics. It is not a surprise -- and maybe this is creeping into Round 2, but it's no surprise that much of the presumed abuse is in a population below age 65, representing a very different demographic

that what might be called the average Medicare patient.

And if we're going to look at opioids, we might want to just consider as we go through this that it might be better to consider opioids in the context of pain control because that's where I think there's some very important issues for Medicare population. It doesn't make this such a moralistic issue if we combine these two together, but maybe I'll have more to say later on that.

MR. HACKBARTH: Okay. I think the barrier between 1 and 2 has been well breached, so you don't need to feel apologetic about that.

Other Round 1 clarifying questions? Jon, did you have your hand up? Herb and then Jack.

MR. KUHN: If I can ask you to go to Slide 12. I am just curious about the first dot point where you talk about the point-of-service edits. I just wanted to understand a little bit more about the challenge CMS was having. You said FDA didn't have clear guidance here, but I know at least on the Part A and Part B side, CMS has a tool, a national coverage determination tool, where even if they disagree with FDA or have additional information, they can put a recommendation out, get public comment, and make

a change in that program. Do they not have a similar tool in the Part D side?

MS. SUZUKI: We don't think so. Having said that, they have issued sub-regulatory guidance on this topic.

MR. KUHN: That may be something that the policy world, we could look at, is what works in the Part A, Part B side when they see these kind of issues. As you say, they do have sub-regulatory guidance opportunities, but if there is something more, not necessarily discrete, but more overt that they could use, that might be something to look at somewhere in the future.

DR. HOADLEY: Just thinking about Herb's question, it strikes me that the plans under prior authorization or things like that would have -- could use things as much softer kinds of things. The issue might be whether Medicare in overseeing Part D could do certain things. That's where I think the question was being asked and answered, but there still would be flexibility on the plan side.

My clarifying questions are on Slide 3. When you talk about statistics such as the opioid users were more

likely to be disabled or receive LIS, did you do any risk adjustment in relation to that? Does any of that go away if you risk-adjust?

MS. SUZUKI: What exactly do you --

DR. HOADLEY: So I mean since LIS beneficiaries are overall sicker, is the level more likely, therefore, to have pain-related kind of conditions -- I mean, in an extreme case, you could say that their opioid use is only appropriate to their otherwise level of health.

MS. SUZUKI: It's not a risk-adjusted figure. We did look at comorbid conditions from the risk-adjustment model to see if you could see whether they had more of certain conditions that could be related to opioid use, and it's not a rigorous study, but we did not see anything jumping out at us saying that this explains why someone would be using opioid compared to other populations.

DR. HOADLEY: Even, for example, to look at people with X number of chronic conditions, is their opioid use within LIS or within under-65 comparable to the other populations with the same number of chronic conditions? Just see if there's any way in which these categories are just surrogates for other kinds of health status.

And on the next slide, Slide 4, when you looked at the top, the high users, you were looking at high users defined by dollars?

MS. SUZUKI: Mm-hmm.

DR. HOADLEY: Did you also take a look at high users defined by volume? I just wonder whether the -- since a lot of the opioids are generics and inexpensive, whether there's anything unique about -- and maybe this is a different kind of question, but is there anything unique about the high-cost ones that would say the high-cost users might actually be a somewhat different subset than the high-volume users? It's a thought to try to further dig into the numbers on this.

MR. HACKBARTH: Round 2 comments. Why don't we just come back the other way and start with Warner and then Jack and Scott and Rita.

MR. THOMAS: Just a comment. I mean, I think, certainly, we could look at a policy of trying to limit or put more regulation in. I tend to think that -- I mean, it's probably not effective long term because I think probably what you have here is you have a lot of other conditions that are happening with the patients. It would

be interesting to think about a broader policy where we try to identify folks that have this type utilization that are, one, in ACOs and can we incent them to try to manage the patient population better or, ones that are not, could there be care management or coordination fees that go with these patients that would incent primary care physicians to really manage what I would anticipate as probably more chronic disease issues that the patients have more effectively, because I think this is a symptom of a problem, not the actual problem, in my opinion.

It would be interesting to kind of look at that more to just see for these users, how many have -- if they're using multiple medications, how many have multiple chronic diseases, and then, once again, what does their other medical utilization look like?

DR. HOADLEY: I mean, this is a really useful starting point for discussions about how to address this in policy, and the problem is it just feels like it's hard.

I've got sort of four thoughts, which I'll just say briefly. One that you did a little more of in the chapter and didn't spend much time on in the presentation was the MTM program, the Medication Therapy Management

program, and I know, Joan, you have talked about this over the years. It's been very frustrating to sort of see the lack of any real results or even sometimes activity. It still feels like if a lot of these people were given the kind of comprehensive medication reviews, if somebody, primary care doctor, pharmacist, somebody sat down and sort of said, "Does this patient really need all these drugs?" that that would help to address it. MTM doesn't seem to have caused that to happen, or when it has, it doesn't seem to necessarily lead to a lot of results.

Second observation. I think you mentioned doing ratings, star ratings, as one potential tool. It does seem like a potential tool. On the Part D side, of course, it has the potential to set priorities. We don't have the payment linkage that we do on MA. So how much does it do? Again, all the usual complications with star ratings, it does feel like it's a potential tool to use in this, although I don't necessarily have super high hopes for it.

Third, you talked about some of the utilization management flexibility, and certainly, that feels like one way to sort of go at some of these cases. We want some kind of stops to be made, potentially. The opioid use is

maybe the easier one to say if somebody has got the nth new prescription, let's stop and make sure somebody has looked at that before we dispense what the possibility of things, like the temporary supplies and stuff like that.

I do think -- and we have said this before in other contexts -- that we really have to think about getting some of the appeals procedures right because too often to patients, the UM process, these are just sort of unthinking barriers to appropriate use as well as a means of slowing down inappropriate use, and we need to figure out how to get that right.

The fourth is just to be careful as we go through this that we're not sort of blaming the low-income patients and we do see -- and that was sort of the source of my question -- you do see the higher levels, and if that holds up after we look at other kinds of factors. And we know there are some differences in how things like copayments and other kinds of things are done, that maybe there is a factor there, but it does feel like sometimes we could fall into the trap of saying, "Well, this is a problem for those patients." It's clearly a problem for a broad array of patients, and I think we should be wary about folks -- and

you didn't push the focus so much on this, but it comes up in these discussions, so I just want to be wary about that.

MR. HACKBARTH: If I could, I just would like to go back to Warner's comment for a second, and I think a piece of what you said, Warner, was, given the nature of these problems, better mechanisms for care coordination like ACOs could be a part of the solution, which I agree with in principle. But I just want to remind people, that's sort of our stock answer to a lot of problems, and here we've got the particular challenge that Part D expenses are not part of ACOs. And the logistical challenge of somehow incorporating Part D expenses, given that they are managed by separate insurers, into ACO assessments, calculations, and the like, there's some real barriers there. I don't know how easy it is to surmount them, but it would require a major effort to try to bring Part D into ACOs and have that part of the medical bundle that is managed by an ACO.

So I just wanted to highlight that again.

MR. THOMAS: So just to comment on that, I would say it's an "and" not an "or." So I would say if there's regulation we want to put in for Part D to try to manage

the utilization of opioids or try to limit access to, I think that could be -- that's one approach that could be taken. And at the same time, let's identify who these folks are and see if there is a way we could, you know, on the other side of the program provide incentives or care management fees that could effectively manage them better from a total medical cost separate from Part D.

Does that make sense, or --

MR. HACKBARTH: To be clear, I didn't -- I'm not trying to disagree with what you're saying --

MR. THOMAS: No.

MR. HACKBARTH: -- but just to highlight that there is this challenge about how Part D expenses integrate with ACOs. Obviously, in terms of Medicare Advantage, the mechanisms for management of drug expenses exist already. But ACOs are somewhat more problematic and challenging.

MR. ARMSTRONG: Yeah, actually my comments are really in the middle of the dialogue the two of you have just been having.

First, I do want to affirm I think this is a very important topic for us to be giving attention to, the overuse, the misuse, the harm caused by the avoidable costs

associated. Opioid use in particular is an enormous issue, and I'm really glad we're trying to figure this out.

I wish I had a better translation of my own experience into policy options or ideas, given the Part D program, just as you were describing. But the point I wanted to make was that there are organizations that are in MA or, you know, with this kind of accountability that have done some spectacularly effective things to change the use of opioids and to improve care and health for these populations of patients.

In my own system, for example, I know every beneficiary in my system who is prescribed an opioid, and we have a care plan for every one of those members. And the outcomes that have resulted from this attention has really been quite spectacular.

I guess my only suggestion would be let's make sure we know what systems that are doing this well are doing and ask how that might inform or begin to, as Warner was saying, you know, complement, if you will, some of the payment policies that we might be able to speak specifically to within Part D.

DR. REDBERG: First, thanks, Joan and Shinobu,

because it's a really excellent chapter and a really important problem because it certainly illustrates another example of more is not better, and, in fact, more is worse when it comes to a lot of the polypharmacy and opioid use.

And I want to start out by reminding us that there really isn't data that this increasing use of opioids is addressing any clinical problem, and, in fact, people have continued pain and continued suffering and just are on escalating doses of opioids and other medications with new problems like addiction and other -- there was just in the paper, I think a town in -- I'm not going to say the state because I can't remember -- where they were having an epidemic of HIV use now because of IV use of these opioid --

MEMBERS: Indiana.

DR. REDBERG: It was Indiana, yeah. And there's a lot of problems associated with it, and not getting where the trouble is. So I think sort of a recognition of that is important, and then the resolve to try to address it on a policy level and on a cultural and medical level, because there are many reasons why we have gotten to this point, some of it being more use of it, but a lot of it being use

of opioids now to medicate sort of pain that, when I was training, you know, 20, 30 years ago, we didn't use opioids for non-terminal patients or else post-op, and now it's used for a lot of sort of maladies that it really doesn't treat.

And I think the suggestions, you know, like the care management and other non-medical approaches, like physical therapy, occupational therapy, counseling, you know, other ways to deal with -- because a lot of this is treating depression. I mean, it's not -- that was the most prevalent condition you identified, and opioids don't treat depression. They kind of numb it.

And the association with low income, it's not even clear to me if it's a cause or effect because it's very hard to work when you're on opioids, and it's very hard to work when you're on a number of medications. And so certainly it can contribute to a nonproductive state as well.

In terms of the policy solutions, you know, things that we could strive for, you know, having one doctor who is in charge of your medications, because a lot of the problem is, as you noted, that you have doctor

shopping. You can go to multiple doctors in multiple states and get multiple prescriptions, and this is not really in anyone's best interest. And also the single pharmacy and the states, I don't know how effective it has been. I'd be interested in hearing the states that have monitoring programs now. I mean, we have -- and I think other hospitals do. We have little alerts for patients that come back into our emergency room repeatedly, you know, asking for narcotics. But you can just go to the hospital across the street, the hospital across town, and so we really need sort of a single pharmacy where we can track medications and know what people are getting and what they're doing to protect them and also because of all the fraud and abuse problems there are with narcotics.

DR. COOMBS: Thank you very much. The chapter was excellent.

A couple of ideas I have. As I read the chapter, some things dropped in my head just because of my clinical involvement with patients who are on both the post-operative, the pain side, and the ICU. And one of the things, as I think about it, the increase in the regulatory requirements for CMEs related to pain control, the Joint

Commission, some of the items that we've actually promoted, the pain control is a good thing and we should try to get to optimal pain control, coincide with that, in addition to intersecting with CPOE and what that means for the rollover for prescriptions, where, when I was in internal medicine, prior to going into anesthesia, partners would actually come into the office, pick up a prescription. That's no longer necessary.

And the other piece of it is I think how patients start on narcotics, how do they get on narcotics. I don't think the provider one day wakes up and says, "I'm going to give you Percocet, hydrocodone." Many times there's an event. It doesn't even have to be a surgery event. It could be a fall. It could be a sprain. And for whatever reason, that gets put in the patient's panel of medications.

So I'd be interested -- I don't know how that could be done, but if possible, looking at the initiation of narcotics, because I think once a medication is initiated, unless there's someone doing ongoing review, the patient's visit may not transpire more than twice a year, and so that becomes an issue, because the medications are

rolled over and there's a 30-day rollover period. And so sometimes it's not even done by the physician necessarily. It may be the NP in the office, or it may be the physician assistant that's rolling it over. And, you know, the cross coverage is another issue which I don't think we could ever get at.

And so the monitoring program in the states vary. Massachusetts has a very good monitoring program. But I would actually look at champions in the area of prescription monitoring exterior to the prescription plans and looking at states that have monitoring as a part of their Board of Registration in Medicine, Board of Registration in Nursing, looking and seeing whether or not that correlates with your crescents from your map and, you know, the map that you had, the Southern crescent, we call it, of the greatest opioid use, and see if there's some correlation with that, because I think if you can pick the champions, you can pick the factors that make a big difference, I think it's a huge issue with drug overdoses and drug-drug interactions. And I think about patients who are on benzos and narcotics at the same time, that's when we get into a lot of trouble.

If I were to pick -- you know, you've got a long list of concomitant medications. I would look at those kind of things, the patients who are on some of the mood disorder drugs, some of the mental health disorder drugs, and if those could be tweaked, because I think those kinds of innovations can actually help practitioners, help providers. And all the other things you've outlined have been really great. It's a great chapter, and I appreciate it.

MR. KUHN: So I want to also talk just briefly about the issue of medication therapy management. I recall when the Medicare Modernization Act was being debated and ultimately adopted in 2003. There were so many people talking about this new benefit, this MTM benefit that was going to be available. And I remember member of Congress after member of Congress talking about these brown-bag audits, that for the first time Medicare beneficiaries could take all their pill bottles, put them in a brown bag, take them to their doctor, take them to their pharmacist, and have an audit done, and life would be great. I mean, things were going to change for the better.

And so there was all this talk 12, 13 years ago

about this. This program now, Part D, has been in place for nearly a decade, but yet we continue to talk about enrollment is low and the program's not effective.

So I guess I just need to understand a little bit more why the enrollment is low and why it is not effective, and part of it is kind of -- I don't know if I fully understand how the MTM is paid for. Is it a Part B benefit? Is it a Part D benefit? Does it have CPT codes that are not well valued? You know, just kind of what are some of the barriers that we're seeing and why we're having this low takeup rate.

DR. SOKOLOVSKY: Well, to answer the last question first, the payment comes out of the funds of the plan. It's not a separate -- Medicare doesn't pay them. The plan pays them, and they have different methods of doing that. Some of them -- sometimes it's an on-staff pharmacist. Sometimes they contract with a third party whose job it is to do this for plans. So that's an easy answer.

Why it's not effective, part of it is that the plans don't have much of a real incentive to do it. Whoever is managing it is not likely to be a geriatrician

pharmacist, because there aren't that many to do all of this. And when I look for -- I haven't been able to find the numbers, but when I look through the reports that have come out, they seem to be more focused on, well, these are drugs that you need and you're not taking them rather than these are drugs that you don't need and why are you taking them. It's more about increasing adherence than eliminating most drugs, unless there are -- you know, they may find duplicate drugs, but they're not going the other way, because they're looking at the guidelines for, say, cholesterol and they want to make sure you're taking a drug for that. They're not really looking so much as interactions between drugs.

So, I mean, at least that's my theory looking at the reports. I haven't done work specifically on it, just that it bothers me.

As far as the enrollment being low, at first it was -- CMS changes the enrollment pattern each year, what the requirements are. But they've tried to get more and more people by making more people eligible for it. The plan has to reach out to the beneficiary, but how hard they have to reach out is not clear. But even if they reach the

beneficiary, the large majority say, "No, I don't want to participate."

So I don't know how it's sold to them that they find it something they don't want, but that seems to be what the evidence indicates.

MR. HACKBARTH: Joan, could you go back to your first statement that the plans don't have a very strong incentive to do this and just say more? Why don't they? I would think if one of their enrollees is using drugs that they really don't need, the plan would want them to use fewer drugs. They're at risk for drug utilization. Why don't they have an incentive to do this?

DR. SOKOLOVSKY: Well, I think this is something that you all have been talking about this year, that when you're taking really a lot of drugs, not too far along, the plans have only 15 percent risk; whereas, paying for the clinicians or whoever it's going to be that personally reviews the drugs and has a meeting with the beneficiary and so on is not going to be cheap.

MR. HACKBARTH: Okay.

DR. MILLER: Well -- go ahead.

DR. HOADLEY: I was just going to -- a quick

follow-up. My impression is that most of these reviews, when they're done, are done by pharmacists rather than doctors, and that they're often done by pharmacists that work for the plan maybe on a telephone line rather than the kind of scenario of walking in with the brown bag to your doctor and saying, "Here it is. What should I be using?" Is my impression correct on that?

DR. SOKOLOVSKY: At the beginning it was any which way, and some plans chose to do it that way, and others didn't. My understanding now is that it's more and more companies, third-party companies who are pharmacists and their job, after they're contracted with by the plan, is to do it personally.

But when we look at what they do, even the annual review of all the medications mostly doesn't happen, even for the people who are participating and who are getting something.

DR. HOADLEY: But they're not working through like the patient's, the enrollee's primary care physician or something like that?

DR. SOKOLOVSKY: No. No, absolutely not.

DR. MILLER: And that's one thing I just wanted

to inject into this, triggering off of his question and what you were saying, and also to be sure that you understood when you talk about participation. I mean, you can reach out, but the beneficiary can or cannot participate. If you're a PDP -- and you know this better than I do -- you know, a PDP, your relationship with the prescribers and the other physicians that are involved in that patient's life is very distant, and we hear a lot of the PDP says I think there might be an issue here, fax stuff over, call up. And it just is kind of waved off by the providers.

You would think in an MA plan, in addition to the drug use and the AB use, the MA plan would have an incentive. But, remember, the MA plan has also other tools, like, you know -- or a greater ability to kind of reach to the beneficiary through a lot of mechanisms. And so I think there's a lot of things that explain your triggering question.

MR. KUHN: And has CMS ever thought or talked about putting thresholds in there that, you know, plans, every year they need to at least do MTM with 30 percent or 40 percent? Do they have targets that they have to hit?

DR. SOKOLOVSKY: Yes, and every year they raise the target in an effort to get more people to participate. But I think, you know, now you only have to be taking two drugs to qualify. But I think that the result of that has been that would be even more expensive, and, therefore, if you're not willing to triple the amount of money you spend on the program, you're working less hard to reach those people.

MR. HACKBARTH: So does anybody else want in on this particular point?

[Laughter.]

MR. HACKBARTH: Okay, Craig and Dave and Kathy, it's on this point?

DR. SAMITT: Yeah, I mean, it's actually on, I think, a bunch of the points, and I end with MTM. I have two perspectives, and they stem from Slide 13, if we can go there.

You know, in my experience, I'm always much more in favor of extrinsic motivators as a means of driving change as opposed to administrative controls, which is what you see on Slide 12. And so I think that the power of the opportunity is very much on this slide, and I think it

falls in two dimensions. One is we need to concentrate very much on this profiling notion. I'm a big believer in this notion of profiling, and I think we should be profiling physicians, I think we should be profiling hospitals and health systems, because we should be looking at who truly is driving high opioid use and polypharmacy. I think they're highly interrelated.

I also completely agree with Alice's views on this because we all should be profiling where the starts are happening. I had mentioned in one of the prior discussions about this that some health systems do an evaluation of what drives patient satisfaction with hospitalizations, and pain control is a big part of it. So we may find that a lot of the starts are hospitalizations, because in many respects they may correlate with patient satisfaction. And I think we should study that. So I very much believe in the notion of looking at incentives for Part D plans and profiling to really look at where the outliers are.

The second concept is really about the need to do both, which is that we need alignment between the payer and the provider. We can't think of extrinsic motivation of

one versus the other. And to Scott's point, I think we look at those organizations that do this very well, what we'll likely find is that exact alignment whereby the plan and the provider both have interests in educating the patient, the beneficiary -- and I would even argue that it's aligned with the beneficiary's interest because management of polypharmacy, management of opioid use produces better outcomes for the beneficiaries, reduces risk, ADEs, and total cost of care.

So I think we need to find alignment between these two parts, and I would guess that what you'd find is where you see that alignment, you see high use of MTM, that these systems maximize it. So we need pressure from both directions to encourage that.

And then the final thing that I would say is I want to comment on the ACO notion, because I'm not sure to create alignment between PDPs and ACOs you need the ACO to be at risk or accountable for the cost of drugs. I would say think of another type of incentive for ACOs. Maybe we should be profiling opioid use in ACOs, or maybe we should be profiling polypharmacy in ACOs, and that is a component of a quality metric. It doesn't have to be the cost

elements of Part D. One would argue they already should be looking at polypharmacy anyway because management of polypharmacy improves the health of the overall population and reduces the total cost of care.

But on top of that sort of natural incentive anyway, I don't see why we wouldn't think of a quality measure that taps to this, plus the incentive for Part D. Those two together, with the ACO population, should offer some policy recommendations to help manage this.

DR. SOKOLOVSKY: I just want to make one comment. I thought about mentioning it before, but now you've pushed me that I have to mention it. There was some literature in the last year about one ACO that requires a clinical pharmacist on all of its Care Coordination Teams, and they have registered quite a bit of success in their MTM program, which is linked to this pharmacist on the team.

MR. HACKBARTH: So, we're still on this same point. I have Dave and Kathy, and Mary, you want in on something else or on this? On something else. Okay. Dave, and then Kathy, and then --

DR. NERENZ: I'll pass. Craig made the point.

MS. BUTO: I'm going to come in on something

else.

MR. HACKBARTH: Oh, okay. Then we're back to Jon.

DR. CHRISTIANSON: So, I thought this was really an interesting chapter, and lots of interesting statistics that kind of jump off the page at you that were surprising to me, and a lot going on. So, you had the polypharmacy stuff, which we've been talking about. We've had the opioid use sort of as an issue in itself, but also as an example of polypharmacy.

But, also in the chapter, you had a really quite long text box that you used to address fraudulent -- I would characterize -- fraudulent use of opiates, and you present some data that suggests it's going on. You describe some of the CMS programs that have tried to identify where that might be occurring. And then you actually propose or raise some issues around policy things that we could consider or recommend.

And, I think the text box was useful in terms of, for me, separating out the issue of there's potential fraud in the use of opiates from the general stuff we've been talking about, like appropriate medical use of this in

treating patients.

So, from the Commission's point of view, I think we at some point will kind of need to make a decision about whether we want to focus attention on the policy issues that you raised and take stands on things related to how do you ferret out and what should you do about fraudulent use of opiates versus the general issues that we've been talking about today. And, I'm not sure that we want to do that. That's what I'm saying. It's a general question about, is this something we want to take on, or do we want to focus more on general issues related to polypharmacy and what most of the discussion has addressed today.

DR. CROSSON: Thanks. I just want to make one comment, and that's about the write-up itself. I don't do this much, because the general quality is so high, but I just found this one particularly well researched, clear, and concise, all of which I value in write-ups. So, thank you, both of you, for that.

I'll talk -- you know, with respect to polypharmacy, I think one of the problems I have in thinking about this -- and this is similar, I think, to something Mark said earlier, is, first of all, the term

itself is fairly non-specific, because it seems to me it's describing at least three different situations.

One is a situation where an individual, a beneficiary -- and as we know, many beneficiaries are on a lot of drugs because of their age and conditions and things -- it describes a situation where, for one reason or the other, the complement of drugs is inappropriate because of drug-drug interactions or all the other things that you've written about.

Another situation is where a beneficiary is on a large number of drugs and they're appropriate for that individual and those conditions, but the management of it by the beneficiary is very difficult, potentially because of confusion that comes with older age. That's a separate issue.

And then the last situation is where beneficiaries are on a large number of drugs and they're perfectly appropriate.

And, I think -- so, I just wonder in terms of how we think about this down the line if we might not get more specific about what we're talking about rather than using a general term, which I think can cause some confusion.

I do believe, based on the data -- I was really shocked to see that close to 25 to nearly 50 percent of Medicare beneficiaries across the age spectrum are on opioids in any given year. I mean, I knew there was an issue. I didn't realize that. I think that screams for some work and intervention.

I think the policy in this regard, the policy options that we should look at, similar to Scott, I think there is an experience out there, particularly in MAPD plans -- and delivery systems are at risk, in general, for pharmaceutical services -- that we could tap to look at mechanisms. Not all of these are going to be applicable to the PDP situation, but some may be.

My thought would be to look at what, in fact, physicians do or don't do, because I think, although I think the MTM thing holds promise, in the loose environment of PDP plans, for reasons already stated, it may not turn out to be that effective, whereas working with the physicians and the physician-patient relationship might well be.

And, so, I would be thinking about looking at this issue of limitation of providers in some way and

focusing on those providers particularly. I think that's what we do in some of the programs I talked about a minute ago. It just struck me in the data that where individuals were accessing opioids from large numbers of providers, it tended to correlate with what appeared to be abuse.

So, I don't know how to do the limitation of providers. I realize the issue of LIS individuals being able to change plans on a monthly basis is a potential objection. I would imagine that an individual, LIS or not, who is changing plans -- who is on opioids and changing plans every month or with some frequency would be a suspicious situation to begin with.

So, I think looking at limitation of providers, exploring the pros and cons of that, policy issues around that might be fruitful.

MR. HACKBARTH: I have Mary, Dave, and Kathy, and Bill. Anybody else on the list? Okay. Mary.

DR. NAYLOR: So, I want to echo Jay's comments about this work and how extraordinarily important it is, I think, for the Medicare program today and well into its future. I think we are talking about a very big issue here around effective and efficient and appropriate use of

medications and all the -- you used the word "cascading" -- implications when we're ineffective and inefficient.

So, I think this might be a case where we would want to -- we talk a lot about bundling, but we might want to unbundle this work, and it's all stimulated by your terrific chapter. I think we might want to unbundle, as you clearly stated that we are talking about different target populations here, and maybe looking at this from the standpoint of -- and, not only to get back to bundling, but of the older adult versus the younger or disabled.

I also think that, as Warren [sic], Alice, and others have said, we might want to look back more to the root cause. Multiple chronic conditions contribute to polypharmacy because clinical guidelines dictate that so-and-so with diabetes needs to be on X, Y, and Z medications, and so on and so forth, and with cancer, and so on. But, as people live longer, they get more of those clinical guidelines and we now know that they don't all -- we know from science that they don't interact. So, I think that that's a really important, kind of going back, the polypharmacy maybe root cause is multiple chronic conditions.

As Bill has, and others, suggested, opioids, if you look at the root cause, has been a societal problem in mismanagement of pain, and we began to think about solving that by adding more and more medications and now it's a big problem, including for the older adults.

I think we then have to think about what are the common facilitators and barriers, and medication management can't be thought of outside of looking at individualized care plans, chronic care management, palliative care, mental health, and teams. We constantly refer to the role of the physician when, in this case, it is a team approach. Pharmacists, nurse practitioners, and others all need to be on the same page with this.

I think, then, finally figuring out what are the best practices and from that deriving policy implications.

The perspectives on which we have to look at this are the beneficiaries, the physicians and other health professionals, the plans, but, most importantly, society and how it views the almighty pill as the way to solve all of our health problems.

DR. HALL: Well, as usual, I agree very much with Mary's sentiments.

The way I would parse this out -- first of all, it's a very, very important area and I think we can really do a lot through our mechanism here. So, I would say that the issue of opioids, just for the record -- I don't know that you mentioned this in the chapter, you might have -- but, there was a huge uptake in the opioid use in the Medicare population starting about 1992, coincident to a clinical guideline that the American Geriatric Society put out, suggesting that opioids might be the drug of choice for pain in older people because the alternative, nonsteroidals, had such serious problems with cardiac and renal function.

So, basically, this was sort of designed to move to a greater use of opioids. Now, that's been modified since then, but -- so, I think the opioids are kind of a special area.

So, it's that area and then there's the use of opioids for people -- seniors who are addicted. That's another -- it's a special problem.

But, then, that leaves -- as a geriatrician, when I think of polypharmacy, it's the large mass of Medicare patients, probably 30 or 40 percent, who are on not just

three or four or five drugs, but are on ten or 12 drugs. This is a commonplace occurrence. This is a disease of medical progress. When Medicare was instituted in 1965, there were about six drugs that may or may not have worked. now, we have a lot of drugs that have improved the quality of life, and particularly in the area of cardiovascular disease, so that we're now left with people on legitimate reasons in the abstract for taking individual pills. But, we know that when we put it together, it can become a disaster.

So, I think the approach of MedPAC might be to say, here is a perfect opportunity to call attention and maybe give some serious thought to interventions that will do two things that are important to us. One is improve the quality of life of older people, no question about that.

But, secondly, vastly reduce the cost of medical care, because as you cited in your chapter and has been noted elsewhere, as many as ten percent of all acute Medicare admissions are due to an adverse drug event. Imagine a situation where one out of every ten admissions to the hospital are related to a misadventure in a common medical practice, amenable to education, amenable to

electronic medical records, prescribing that's electric, which is starting to really catch on around the country.

So, we get a big whammy on this, two good benefits, quality of life and reduction, potentially -- it's not the cost of the drug that's the issue here. It's really the sequelae of adverse drug events. That's how I look at this.

DR. CHRISTIANSON: Dave, I think you were next, and then Kathy.

DR. NERENZ: No, actually, Craig said a long time ago what I was going to say.

MS. BUTO: Okay. I just have a few comments. One is, I really like this slide. I would suggest we think about adding two more bullets to it. One would be something about finding a way to increase or actually create a feedback loop between Part D plans and primary care physicians or prescribers. There's got to be a way. There's been a tremendous amount of money spent on electronic records. Isn't this one of the best test cases for activating that electronic communications pathway? So, I would just say, I think that's a challenge, but we really should urge that that be done, and we might have some ideas

as to how we could achieve that.

A second one, or another bullet I would suggest we look at is beneficiary engagement, so -- especially in the opioid area. That's an area where there is a lot of engagement by law enforcement authorities looking to prosecute physicians who are big prescribers of opioids and abusers and so on, and, I think, Jon, this is where it intersects your issue or your note.

There's a whole area of protocol development about the appropriate use of opioids that I think could both -- could be sort of a bridge between appropriate medication management and the issue that you're raising about should we be even talking about fraud and abuse. There's an intersection there. Without good communication about protocols, I think we do lend ourselves to a lot of fraud and abuse in this area of prescribing.

And, you know, CMS may have done this. I don't know. But, I don't think it's well understood what the appropriate protocols are. And, again, plans don't seem to have a strong incentive to put these forward and actually to follow them.

So, back to your, which I really like, your

bullet point on quality and performance measures tied to payment, those are -- that authority obviously exists, but hasn't been really used. Or, maybe it's being used, but not for the kinds of things that we think are -- it could be sort of ratcheted up to do.

I think this is an area, whether it's, you know, Part D plans, we know, collect data. Surely, they are tracking for their individual subscribers how many physicians are prescribing. They must know who the physicians are. They must have a way of tracking that. It just seems to me we're not holding them accountable for this whole polypharmacy area, and if we want to focus on opioids, on that area, and that there's more ability to tie that to performance measures and payment that might make this a more kind of robust requirement.

So, I really like that one, and I would look at what we could do with beneficiaries and also with feedback loop to doctors.

MR. HACKBARTH: Okay. Jack, last word.

DR. HOADLEY: A quick follow-up to a couple of questions. People have mentioned electronic records and electronic prescribing. It might be useful in some future

presentation on this or some of the other related issues to sort of get an update on where things stand on e-prescribing. There's been a lot of talk about all the things it can do for formulary adherence, for other kinds of things, and yet I keep hearing rumbles that it doesn't quite do the things that we've kind of hoped it will and it might be something where we could just sort of see, what's the state of play? Is there anything we can do to help if it's not where we want it to be?

MR. HACKBARTH: Okay. Thank you, Shinobu and Joan. Well done, as usual.

We'll now have our public comment period.

[Pause.]

MR. HACKBARTH: And, before you begin, let me just see -- just two people wanting to make comments? Okay.

Let me just quickly repeat the ground rules. So, begin by identifying yourself and your organization. When the light comes back on, that signifies the end of your two minutes.

MS. RILEY: How long is the time? I'm sorry.

MR. HACKBARTH: Two minutes.

MS. RILEY: Two minutes, okay. Great. Thank you very much. Good afternoon. My name is Cindy Riley. I am a pharmacist and Director of the Prescription Drug Abuse Project at the Pew Charitable Trusts. Pew is a nonpartisan research and policy organization with a number of drug and medical device initiatives. Thank you for addressing the topic of polypharmacy today.

Doctor shopping, or visiting multiple prescribers and pharmacies, is one mechanism to obtain excess quantities of opioids and other controlled substances. This practice, which often results in polypharmacy, may be addressed through the use of patient review and restriction programs, or PRRs. These programs identify, as we've heard here today, patients suspected of abusing prescription opioids and designate a single pharmacy or prescriber. The result is improved care coordination that ensures patient access to needed medications while lowering the risk of overdose.

In January, Pew submitted a letter to MedPAC that recommended that Congress provide Medicare Part D plan sponsors the authority to implement PRR programs. I won't go into the details of that letter here, but I will tell

you that you will hear we've described in that letter some statistics that were outlined in reports by CMS and GAO that are similar to the statistics that were presented by Ms. Suzuki here today, as well as at your earlier meeting in October of 2014.

As you've heard, there are other tools that can address inappropriate opioid use in Medicare Part D. CMS recently proposed an expansion of its current Overutilization Management System, or OMS. While OMS has demonstrated some effectiveness in addressing overuse of opioids, a recent analysis that was contained in their 2016 Advance Notice and Call Letter demonstrated that there was a high frequency at which beneficiaries repeated exceeding the established threshold, even after following an intervention. This indicates that currently available mechanisms have limited effectiveness. While the proposed changes to the OMS may enhance identification of patients at risk, this change would continue to rely predominately on retrospective interventions.

A PRR can prospectively improve opioid use while applying safeguards that ensure beneficiary access to needed pain therapies. An evaluation performed by the CDC

expert panel found that PRRs used in State Medicaid programs have generated savings and reduced narcotic prescriptions, abuse, and visits to multiple doctors and emergency rooms. About 45 States currently have PRRs in place, and they are also widely used in private plans.

Current law does not allow the use of PRRs in Medicare Part D plans, despite the fact that officials from CMS have indicated a willingness to explore their use. There is significant bipartisan momentum building for change with legislation that has been considered by Ways and Means as well as the Energy and Commerce Commission in the House.

Is that my light?

MR. HACKBARTH: Yes, it's your light.

[Laughter.]

MS. RILEY: Okay. Again, I'd like to thank you for your time here this afternoon. Pew has additional comments in our letters that we'd be willing to share.

Thank you very much.

MR. HACKBARTH: Thank you.

MS. COHEN: Good afternoon. My name is Allison Cohen and I'm with the Association of American Medical

Colleges. The AMC appreciates this opportunity to share our views on the recommendations related to short-stay payment issues.

The AMC commends MedPAC for acknowledging the challenges associated with the 2-midnight rule and for recommending withdrawal of this flawed policy.

At the same time, the AMC supports leaving in place the part of the 2-midnight rule pertaining to stays longer than two midnights, because this part of the rule alone effectively reduces longer observation stays that this policy was adopted to correct.

We also strongly support MedPAC's recommendation to hold recovery audit contractors accountable by modifying RAC contingency fees, to subject RACs to a penalty if their overturn rate exceeds a certain threshold. For important policy reasons, the AMC has serious concerns about the recommendation directing RACs to focus on hospitals with the highest rate of short-stay cases because it may improperly target large hospitals and major teaching hospitals and disincentivize innovating to efficiently treat complex patients.

The Association's data analysis demonstrates that

hospitals do not vary substantially in their share of short-stay cases as a percentage of all cases. Instead, hospitals' average number of short-stay cases increases for larger hospitals and hospitals with more Medicare inpatient volume. The AMC is concerned that targeting hospitals with higher average number of short stays would merely target larger hospitals that treat more Medicare patients.

If MedPAC chooses to adopt this recommendation, the AMC strongly encourages the Commission to require a risk adjustment to ensure that hospitals that take care of the most Medicare patients and have innovated to treat the most complex patients efficiently are not improperly targeted.

For the same reasons, the AMC is also opposed to evaluating replacing the RAC program with a formulaic hospital penalty imposed on hospitals with a higher volume of short stays than other hospitals.

Thank you for the opportunity to present our views.

MR. HACKBARTH: We are adjourned until one.

[Whereupon, at 11:47 a.m., the meeting was recessed, to reconvene at 1:00 p.m. this same day.]

AFTERNOON SESSION

[1:00 p.m.]

MR. HACKBARTH: Okay. It's not everybody who gets to do sharing Part D risk after lunch. Do you know how -- this is like an actuary's dream, right?

[Laughter.]

MS. UCCELLO: Every day.

MR. KUHN: It's the highlight of our day.

MR. HACKBARTH: Okay. We are off. Rachel and Shinobu.

DR. SCHMIDT: So, Cori, this is for you?

[Laughter.]

DR. SCHMIDT: Good afternoon. Today we'll pick up where we left off last month in your conversations about how Medicare shares risk with plans in the Part D program. We plan to include this material in our June report to the Congress.

In this presentation, I'll review some of what we talked about last month in terms of patterns we've observed in Medicare's payments to plans and what we think may be a financially advantageous way for plans to bid. Next we'll look in more detail at what might happen if Medicare were

to lower the amount of individual reinsurance that it provides to Part D plans. An alternative to Medicare's reinsurance might be for plan sponsors to purchase private reinsurance, so we'll discuss that option. We'll also discuss options for changing Part D's risk corridors and go over Medicare's new requirements for medical loss ratios to see if they serve a similar purpose as the risk corridors. I'll end with our plans for going forward.

This slide is a reminder of the ways in which Medicare shares risk with private plans. The direct subsidy is the name of the payment that Medicare makes to all plans each month to lower the cost of premiums for all Part D enrollees. Since it's a capitated amount, the plan sponsor bears insurance risk. If their plans' enrollees spend more than the direct subsidy they get from Medicare and enrollee premiums combined, the plan has to cover the cost. Second, Medicare risk-adjusts the direct subsidy to offset the incentives for plan sponsors to avoid higher-cost beneficiaries.

Medicare pays individual reinsurance for each plan enrollee with drug spending above Part D's catastrophic threshold. And if, across all a plan's

enrollees, the plan's aggregate benefit costs are a lot higher or lower than what it bid, Medicare shares in the plan's losses or profits through risk corridors.

Remember last time we talked about CMS' process for reconciling Medicare's prospective payments to plans with their actual benefit spending. We talked about how we've noticed a pattern in the payments that come out of the reconciliation process. In recent years, for a growing majority of sponsors, Medicare ends up paying out more individual reinsurance money to the plans when they reconcile the payments. The positive amounts (in yellow bars) mean Medicare paid the plans. In other words, the plan sponsors have been underestimating how much of their covered benefits would fall in the catastrophic part of the benefit.

The reconciliation data also show us that in each year since Part D began, plan sponsors have, in the aggregate, paid Medicare back through risk corridors. Negative amounts (in the green bars) mean the plans paid Medicare because sponsors overestimated all the other covered benefits in their bids except for catastrophic spending. So plan sponsors have had to pay back Medicare

in the risk corridors because they were overpaid in their prospective payments. They made additional profits through the risk corridors above and beyond the margins that they had already included in their bids.

So just to summarize the pattern, at reconciliation, Medicare paid most plans more for reinsurance because they bid too low on catastrophic spending, and then the plans paid Medicare through the risk corridors because plan sponsors bid too high on the rest of benefit spending other than catastrophic coverage.

Last time, we told you that we had interviewed plan actuaries to get their take on why this pattern might be happening. They told us that there is a lot of uncertainty about key assumptions when they have to submit bids to CMS and the way in which some plan sponsors project future spending growth could lead to underestimates of catastrophic spending. However, we've seen a persistent pattern rather than randomness in payments that we might expect to see in the face of general uncertainty. The persistence of the pattern led us to ask whether there might also be financial advantages to bidding in certain ways.

In March, Shinobu walked you through a numeric example of how underestimating the catastrophic spending in bids could potentially help a plan's financial position. Bidding this way could help the plan keep a competitive premium and yet the plan would still be guaranteed to recoup any higher actual amounts of catastrophic spending from Medicare through reinsurance reconciliation payments. In addition, with the risk corridors, if a plan's benefit costs are 5 percent lower than its bid, the risk corridors let the plan keep all of that difference as additional profit above and beyond the margin that was included in its bid. If the plan's actual benefit costs are even lower, it has to return some of that to Medicare, but it gets to keep some. A downside of this bidding approach is that the plan would have somewhat less cash flow because its prospective reinsurance payments would be lower.

So as we consider policy options for risk sharing, one approach might be to lower the amount of individual reinsurance that Medicare provides. I won't go over this slide of the standard Part D benefit in detail again, other than to call your attention to the white area at the top. Medicare pays 80 percent of benefit spending

above the catastrophic threshold, while the plan pays 15 percent and the enrollee pays 5 percent. That cap is currently at about $7,000 in total covered drug spending. Because Medicare pays for 80 percent of covered benefits above that amount, it's taking a lot of the risk for the highest spending enrollees.

Here's the same slide, except that to demonstrate one option, I've changed the top. Notice that Medicare's individual reinsurance (again, in white) is now just 20 percent of catastrophic spending. It doesn't have to be 20 percent. This is just an example. We've used this example because now the plan is responsible for covering 75 percent of benefit spending above the catastrophic threshold just as it covers 75 percent of spending between the deductible and the initial coverage limit. The idea behind this change is to give plan sponsors greater incentive to manage benefit spending even among high-cost enrollees who reach the catastrophic portion of the benefit.

You might be concerned that lowering Medicare's reinsurance would lead to much higher enrollee premiums. Let's look at that for a minute. Here I'm using the same hypothetical example that we provided in your mailing

materials, with a simplified benefit structure that's different from Part D's actual benefit. The middle column shows current policy in which Medicare pays plans for 80 percent of benefit spending above the catastrophic limit. In the right column, we've got what might happen if Medicare only paid 20 percent reinsurance. This is a very simple example that assumes there would be no behavioral changes, so it's just cranking through the formula for Part D subsidies. For the same $50 that a plan expects as catastrophic spending in its bid, Medicare would pay $40 to the plan under current policy, but only $10 with the lower reinsurance rate. That means the plan sponsor would be at risk for more of the benefit spending -- $37.50 in benefits above the catastrophic limit compared with $7.50. When you add the rest of benefit spending in, the plan would now be at risk for $90 of the benefit rather than $60. The expected cost of the total benefit would be the same in both cases ($100); it's just that the plan would be at risk for more of it.

Part D law says that enrollees must pay 25.5 percent of benefits, so in this case, that's a premium of $25.50 per month. In the example, the enrollee premium

wasn't affected. Even though Medicare reduced its reinsurance, it had to keep its overall subsidy at 74.5 percent, so it would pay plans more in monthly capitated payments: $64.50 instead of $34.50. Now, again, this is a very simple example assuming no behavioral changes. However, requiring plan sponsors to bear more of the risk would likely affect their behavior. On the one hand, there might be downward pressure on benefit spending because bearing more risk would give sponsors more incentive to manage drug spending. At the same time, there might be some upward pressure on benefit costs because plan sponsors might need to purchase private reinsurance or otherwise recoup a premium for bearing more risk.

If Medicare had lower reinsurance, would that affect the bidding incentives that Shinobu described to you last time? We suspect that so long as Medicare guarantees to make the sponsor whole for some of its actual benefit spending as they do currently through reinsurance, there will still be an incentive to bid in a financially advantageous way. However, by giving more of Medicare's subsidy through capitated payments, the relative amount of dollars provided through reinsurance would be smaller --

which would temper the incentive somewhat.

One concern about lowering Medicare's reinsurance might be that plan sponsors might not have the capacity to bear more risk. However, about 80 percent of Part D enrollment is in plans operated by nine large insurers. Most of those same companies also offer Medicare Advantage plans and commercial health plans. We believe most would have the capacity to develop internal systems for reinsuring themselves. However, if Medicare provided less reinsurance, smaller regional sponsors might need to purchase private reinsurance. We asked representatives of the reinsurance industry whether they would be interested in extending coverage to the Part D market. Now, this is a different group of actuaries with private reinsurers than the interviewees I described last month who were with Part D plans. The reinsurance actuaries told us that they already have contracts in place with some insurers that offer Medicare Advantage plans, and yes, they'd be willing to offer reinsurance. They see drug spending as having no more variation than medical spending and, for Medicare Advantage plans, they could probably roll drug spending into their existing reinsurance contracts. They would also

be willing to offer private reinsurance for stand-alone drug plans. Among the contracts reinsurers offer to health plans today, it's more common to use an approach like individual reinsurance than risk corridors (where they provide one-sided protection in the event of large plan losses). Reinsurers do offer both kinds, but it would look different from what Medicare's risk sharing looks like. For individual reinsurance, private reinsurers tend to set the point at which they provide coverage higher so that maybe 1 percent to 3 percent of a plan's enrollees hit that level of spending. By comparison, in Part D, currently about 8 percent of enrollees reach the catastrophic threshold. And if private reinsurers were to offer coverage similar to a risk corridor, it would likely be wider than what Medicare provides today. So Part D plan sponsors wouldn't be able to offload as much of the risk through private reinsurance as what Medicare takes on. Most reinsurers were unwilling to estimate what their premiums might cost without more specific details, but one consultant suggested that premiums could be in the range of 20 to 25 percent of covered benefits, where covered benefits would be smaller than what Medicare covers today.

A separate set of options would be to remove or change Part D's risk corridors. This slide shows the corridors that were used in 2006 at the start of Part D at the top when plans may have needed extra help with risk to get this market up and running. The current structure of the corridors is in the middle, and one option for wider corridors is at the bottom. After the end of the benefit year, CMS compares each plan's actual benefits paid with what the plan sponsor bid. In the original risk corridors, the sponsor had to pay for all benefit spending that was up to 2.5 percent higher than what they bid, and they got to keep any profits up to 2.5 percent lower than their bid. Those were additional profits above and beyond the margin that they had already included in the bid.

If actual benefit costs were between 2.5 and 5 percent more or less than the bid, then Medicare and the plan split losses or profits 75/25, with Medicare having the bigger share.

If actual costs were more than 5 percent different from bids, then Medicare paid for 80 percent of larger losses -- or got 80 percent of the gains.

After 2008 the corridors widened, meaning that

plans had to bear more risk -- which is what the law intended. The middle bar shows the corridors that we still have today. The point at which Medicare starts sharing losses or profits is wider -- plus or minus 5 percent around what the plan bid instead of 2.5 percent. Given that plan sponsors have been returning overpayments to Medicare each year through the risk corridors, one perspective may be to tighten the corridors again so that Medicare can recoup more of the overpayments. On the other hand, if the plan knows that Medicare will cover a lot of its losses, it may be less motivated to manage its enrollees' drug spending. In the third bar at the bottom, plan sponsors would be on the hook for all losses up to 10 percent higher than its bid. However, with the payment patterns we've observed, the sponsors would likely be keeping additional profits beyond what they're getting today.

In isolation, you might think that removing the risk corridors is a good idea because plan sponsors would have a lot more incentive to manage their drug benefits. This is in line with the approach used in Medicare Advantage, which doesn't have risk corridors.

However, in practice, Part D's risk corridors aren't just operating in isolation. Medicare is also providing a guarantee to pay individual reinsurance based on enrollees' actual benefit spending. Given the approach to bidding that we think we're seeing in Part D, the risk corridors have acted as a constraint on Medicare's overpayments to plans. Because Medicare has been collecting funding back from plan sponsors each year, we also think that removing the corridors would likely be scored as a cost in legislation.

One idea, then, is to keep the corridors in place for the near term, but potentially make other changes to Part D's risk sharing -- perhaps lowering Medicare's individual reinsurance -- and then revisit the idea of removing the corridors in the longer term.

Cori asked us to look into another issue that's related to Part D's risk corridors: new rules as of 2014 that Part D (and MA) plans meet an 85 percent medical loss ratio requirement. Her question to us was whether the new MLR requirement serves the same role as corridors.

First, let me tell you about the requirement. We don't yet have any data for you because it just went into

effect with the 2014 benefit year, and CMS hasn't yet reconciled claims for that year. But the idea is that each Part D contract's spending on benefits and quality-improving activities must be greater than or equal to 85 percent of total contract revenues. If the contract's MLR is less than 85 percent, then the sponsor has to return the difference between that and 85 percent to Medicare. If the sponsor's contract is out of compliance for three consecutive years, it becomes subject to enrollment sanctions. If it is out of compliance for five consecutive years, CMS will terminate the contract.

MLR requirements act in the same way as a one-sided risk corridor because they try to limit administrative costs and profits to 15 percent of contract revenues. However, the specific definitions of what goes in the numerator and denominator matter, and it's not yet clear how binding a constraint the MLR requirement will be. For example, we're unsure about what will qualify as quality-improving activities or how thoroughly those will be checked. We'll keep our eye on how the MLR plays out and report back to you about what we find.

This slide points out that as we consider changes

to risk sharing, it's important to bear in mind that low-income subsidy enrollees are not distributed evenly across Part D plans. Among all Part D enrollees, about 30 percent get the low-income subsidy. If you look at the 20 stand-alone drug plans that had the most enrollment in 2012, ten of those only had 25 percent or fewer of their enrollees with the LIS and six plans had 75 percent or more with the LIS. So plans tend to either have a small share or a large share of LIS enrollees.

This point about an uneven distribution is important because if risk sharing arrangements change -- for example, if Medicare started paying less than 80 percent in individual reinsurance -- it could disproportionately affect plans that have high shares of their enrollees with the low-income subsidy.

If there are changes to Part D's risk-sharing arrangements, it will be very important to recalibrate the risk adjusters. Otherwise, some sponsors may decide that changes to risk sharing may make it less desirable to enroll beneficiaries with the low-income subsidy.

As for next steps, we're very interested in hearing your comments related to individual reinsurance,

risk corridors, bidding incentives, and the direction of policy options for risk sharing in Part D. We plan to incorporate your comments and turn this material into a chapter in the Commission's June report to the Congress.

For the next cycle, we will bring back to you potential policy options and their implications for beneficiaries, plan sponsors, and Medicare. We may also want to revisit our recommendation on low-income subsidy cost sharing from 2012, as one of several policy options focused on the LIS.

MR. HACKBARTH: Okay. Thank you.

So would you put up Slide 3, Rachel? So if you look at the middle two rows -- risk adjustment and individual reinsurance -- the objective, broadly stated, is the same in each case. So for me, decidedly, as you well know, not a numbers person, that raises the question, well, in judging what we should do with individual reinsurance, we may want to know how good the risk adjustment is, that the two are related to one another.

So analytically how can we assess how good the risk adjustment is and then use that to help guide the decision about whether lessening the individual reinsurance

is a good idea?

DR. SCHMIDT: Well, we haven't done a sort of analytical work like Dan Zabinski has done for the Medicare Advantage program, although we could, you know, think about doing some of that going forward.

I can tell you, in the past, the risk adjustment for low-income subsidy enrollees has been an issue. We've done some work in the early years of Part D where it seemed to be a concern. It seemed that some plan sponsors did not want those enrollees.

CMS subsequently redeveloped its RxHCC model, and I can tell you anecdotally, in the interviews that we conducted plan actuaries, none of them voiced that as a big concern at this point in time, with the possible exception going forward of some of the high-priced specialty drugs, that those -- you know, given that they're entering the market quickly, the expense is large, they won't be reflected in claims very quickly. There's a lag between the recalibration of the risk adjusters and the incorporation of those expenses.

MR. HACKBARTH: Clarifying question? Let's go with Jay and then Bill.

DR. CROSSON: Thank you, Rachel and Shinobu. Another good chapter. Appreciate it.

I will stick with this slide because one of the things I wonder about in the presentation is whether in fact in the future we're going to see more variability in payments and cost and risk from drugs than, for example, the experience in MA plans. At least the recent experience with hepatitis C drugs suggests that, and if any of you watched the wonderful series this week on cancer and the presentation of future potential treatments, immunologic and otherwise, for cancer, it does tend to suggest that downstream costs for biopharmaceuticals are going to add to the unanticipated and potentially unplanned-for risk, anyway.

In looking at individual reinsurance and risk corridors, you introduced this notion for risk corridors that, in fact, one feature is protection against unanticipated spending due to the introduction of expensive drugs, but reinsurance would do that as well, correct, or not?

So is there a reason to believe that the risk corridor is a better protection, either financially or from

a policy perspective, for that problem than individual reinsurance, or did you just choose that to put that example there for the heck of it?

DR. SCHMIDT: Probably more of the latter, I would say.

[Laughter.]

DR. MILLER: I was just going to say, do you want to get a lawyer before you answer?

DR. SCHMIDT: Please.

You're right. They both can serve in that capacity. I don't know. If you start tinkering with the individual reinsurance, one could argue that maybe that might change the incentives again for the plan sponsors to be a bigger part of the negotiation of the price or to think through when it's best to use those high-priced medicines to be more involved in all of that decision-making. I don't know if that might sway you towards keeping the risk corridors in place for just picking up the risk associated with doing that.

Do you have something else?

MS. SUZUKI: The one thing I would add is risk corridors right now covers a different portion than what

the individual reinsurance covers, and if you remember the benefit graph, the 80 percent, that white part, is the individual reinsurance, and risk corridor is around the benefit that's not the white part.

DR. SCHMIDT: [Speaking off microphone.]

MS. SUZUKI: Right.

Right now, only 15 percent of the high cost is actually under the risk corridors.

DR. MILLER: The way I -- not at the technical level -- kind of thought about that is the two devices and particularly at the construction of the program way back in the day were you can have a patient, individual patient experience go south on you, and you want to ensure against that, and because this industry was so new and these things didn't exist in nature, there was real worry about you could just get the whole thing wrong, your whole bid and estimate over time.

What Shinobu is saying is that the individual insurance piece isn't really part of the corridor calculation, and it was thought through that way at the inception of the program.

DR. CROSSON: Can I state it one other way?

Let's say in any given year, any given plan had $100 million additional expense due to the introduction of some high-cost biopharmaceuticals, and we had a world where we either had removed the risk insurance or reinsurance or removed the risk corridors or weakened them, but let's just for the argument's sake say we only have -- we have got belt and suspenders now. We won't have either a belt or suspenders. Either financially or conceptually, what would the difference be to that plan in that situation if we had only reinsurance or if we had only risk corridors?

MS. UCCELLO: Can I just add something in here? I think part of the difference maybe between the -- after the introduction of something that was unexpected, that reinsurance and risk corridors are going to act differently over time. So you can think of in the first year is when there is the surprise, and that the risk corridors kind of take precedence in a way. Over time, plans should be incorporating those costs into their expectations, and now it's coming out in the long term on the reinsurance side of things.

DR. MILLER: I hate to say this in public, but I thought that was really well put, Cori.

[Laughter.]

DR. MILLER: You're an actuary, right? I think she nailed that well.

To his example --

MS. UCCELLO: Can I leave for the day then?

[Laughter.]

DR. MILLER: Oh, you don't understand how the prizes work. You have to stay. You get it wrong; you get to go.

But just to deal with this question a little bit in isolation, I feel very adrift here. So all three of you are on point.

I mean, I would say to the extent that the introduction of this new drug, if that was your example -- I'm a little bit distracted -- and it hit the non-catastrophic portion of the benefit in a systematic way, so that even a person who didn't hit the catastrophic was taking the drug, the corridor might accommodate that.

So, in your example, if the corridor were eliminated, the plan might be running into some heavy water at the lower end of its benefit where it assumed a bid and that bid turned out to be wrong because this thing showed

up.

But then, of course, you would have -- if this is an expensive drug, taking an expensive drug is going to make you more likely to hit the catastrophic cap, and so you could have people who drive into a catastrophic cap because of the introduction of the drug, and the other one, the catastrophic cap takes place.

To go to your example, if you had a catastrophic cap but not corridor and this thing had an effect and it had an effect on the non-catastrophic portion of the benefit, the plan might be losing money because it bid at one level, and it turned out that was wrong. But to the extent that individuals were hitting it, they would be indemnified or at 80 percent or whatever the right word is.

The reverse is also true. So if this drug hit and I had the corridor, I would be indemnified about the fact that I was surprised. I didn't anticipate it, but to the extent that beneficiaries are hitting the catastrophic cap, I wouldn't be indemnified, individual beneficiaries.

MR. HACKBARTH: I think Cori was clearer. So she says and you go.

[Laughter.]

DR. MILLER: Actually, that's fine.

MR. HACKBARTH: Are we good?

Okay. Still on this same issue, I have Jack, and then anybody else want in on this topic?

Jack.

DR. HOADLEY: To some extent, experience -- and we don't have the data on it yet except for what CMS has sort of said publicly -- for 2014 and the hepatitis C drugs is that because those drugs were very expensive for a relatively small set of people, they mostly pushed people into the catastrophic, and most of that additional cost is picked up on the reinsurance side. Speculatively, the risk corridors weren't called in, and both using sort of Shinobu's example from the last meeting and the way you sort of play those numbers through and just the numbers that have already been reported, it would look like that played out.

If what you had was a new drug that was a new cholesterol drug, not a big blockbuster or many thousands of dollars, but a new Lipitor that was at the brand level that was going to affect a lot of people, that might play out differently. But if you take one or the other out,

you've got some ability for whichever one was left in place to pick up the slack of which -- whatever one wasn't there. So that is the sort of reinforcing, you know, if you don't have the belt, the suspenders will do more, and if you don't have the suspenders, the belt will do more. So I think that's -- but the design is a little bit different, and the incentives creates, which we can come back to in the broader discussion, will be different.

MR. HACKBARTH: Is it on this point, Kathy? Yeah. Okay.

MS. BUTO: I think so.

We're still on clarifying questions, right? So the question I have is whether Medicare Advantage plans, when a new procedure comes along that's really expensive, say liver transplant, does CMS still -- I'm looking at Carlos -- still provide sort of a bump-up payment to account for that? In other words, what I'm trying to get to is not only the MLR, but I think CMS Medicare uses other mechanisms to account for the high-cost procedure in the context of Medicare Advantage, and you could imagine that even if they did away with the risk corridors, you could do something like that for an expensive new drug.

DR. SCHMIDT: And Carlo sis nodding yes.

MS. BUTO: Yes. Okay.

MR. ZARABOZO: [Speaking off microphone.] -- national coverage.

DR. SCHMIDT: Right. Yeah. This actually came up last meeting as well. If there is a national coverage decision, then, yes, CMS does make accommodation for that.

MR. HACKBARTH: Anybody else on this point?

[No response.]

MR. HACKBARTH: No? So we're doing clarifying questions, and we'll go down this row. Bill.

MR. GRADISON: On Slide 11, I have a question, please. Looking at the 2006 and now the current division of the cost, has the shift during that period, which as I understand it has increased the risk taken by the plans, caused them to purchase more or any private reinsurance? Have they felt that necessary with that shift so far? That's a question.

DR. SCHMIDT: With the private reinsurers that we spoke with, no, they generally haven't felt the need to purchase private reinsurance, even with that change in the corridors. The provisions within Part D itself were

sufficient, and they're large insurers to begin with, so they had the capacity at that time.

MR. GRADISON: Thank you.

DR. NERENZ: I have a big clarifying and a little clarifying question.

It seems like last time we talked about this -- I'm looking at Scott -- I think Scott was the one who asked, "What's the problem here?" So I'm feeling that same question again. As we go through this discussion, is the issue somehow that the Medicare sharing of risk is too high, relative to the plan? Is it the other way around? Is it wrongly configured even though the balance is right? How do you want us to think about that big thing?

DR. SCHMIDT: I didn't include the slide that we had in the last presentation that was supposed to be more of the motivation behind this whole thing, but we have seen such rapid growth in Medicare program payments associated with risk sharing and particularly for individual reinsurance, that that has been a motivation behind this work.

DR. NERENZ: Okay. Well, that's a perfect transition then to my little question, which was going to

relate to Slide 4, and I think -- and maybe you just answered what I was going to ask. Is the difference in up height versus down height a problem? Is that a restatement of what you just said?

DR. MILLER: I would say this. What Rachel was just referring to is the yellow bars where we can see this ramp-up of individual reinsurance payments, and we're wondering what's going on and then asking the question to your first bigger question. Is the risk structure properly between the Federal Government and the plan? Because the Federal Government is paying out increasingly more insurance dollars, and this could be corrected. We're not, but our intuition is, "Well, wait a minute. The actuaries and the people who think about this should, after 10 years of experience, have some sense of that." But there's also noise, so we're trying to be balanced about it.

The way I think about the risk corridor side of things is almost the same intuition. The plans are paying out under the corridors on net, and once again, if you had 10 years of experience or about 10 years of experience, you might think you could get your bid in such a way that you wouldn't have to pay that, and so we're just sort of asking

-- and this goes on the yellow bars against the government. It goes on the green bars to the government, and we're just sort of saying, "What's the risk structure here? Maybe we need to rethink this."

Remember way back in the day, it was belt and suspenders because nobody had a really good sense of what was going to happen.

DR. NERENZ: Okay. And actually on that metaphor, are the pants actually falling down, or are they not?

[Laughter.]

MR. HACKBARTH: So for me, Dave, it's not so much the net difference between the two. It's the trend on the two lines respectively, the individual reinsurance with this sharp upward bend and then the flatness and the one-sided nature of the green bars.

DR. SCHMIDT: Right. I was going to say these are -- this is kind of a little complicated because there are reconciliations to prospective payments, not the absolute amount of spending.

DR. NERENZ: Well, okay.

DR. SCHMIDT: But yes.

DR. NERENZ: Again, thank you. This is a wonderful answer to my question because that's where I was also going to go. If this is reconciliation, so that really we're just talking about a matter of who guesses what at the beginning of the year and are they up or down, we may conclude that even though one bar goes up and another bar goes down, there's no really net flow of funds or a funny sharing of risk. It's just a matter of how people guess at the front end.

But on the other hand, you could look at it and say, "Well, there's effectively a subsidy going on here." Again, your answers are helping here.

DR. SCHMIDT: Right. And we hope to come back to you with more information looking at the absolute dollars of program spending.

MR. HACKBARTH: So we're continuing on clarifying questions, and we'll go around this way. Cori is next.

MS. UCCELLO: So I've gotten some feedback that I think you've gotten as well about the example and about bidding strategy with respect to the reinsurance and how base premiums are set nationally, and so the ability of any particular insurer to influence that.

I just kind of want to hear your reaction to that with respect to the strategy.

DR. SCHMIDT: Right. So Cori is characterizing accurately a reaction we've gotten back. How can anyone plan sponsor affect things very much, given that it's a bid, a nationwide average bid?

One thing that we heard in the course of doing interviews with plan actuaries is that a lot of them are using the same consulting actuaries who have the same models for projecting growth and spending. Here is one hypothesis, that they kind of fell into a pattern maybe of understating catastrophic coverage, those benefits, and overstating the rest by using a smooth assumption about projecting trend. But over time, maybe there is a financial advantage that becomes obvious to doing it. So that's one hypothesis.

MR. HACKBARTH: Clarifying questions? Jay.

DR. CROSSON: Just on redirect, so Cori --

[Laughter.]

DR. CROSSON: I'm probably getting this wrong again, but does that slide there, with a relative consistency of the risk corridor and the spiking

reinsurance numbers, does that suggest, based on what you said earlier, that this is indicative of relatively unpredictable but short-term changes in unanticipated risk or not?

MS. UCCELLO: The risk corridors have been payments for plans to the government. So, I mean, that kind of makes things a little more difficult to answer this, but I think that the surprise that -- maybe if you want to call it -- this surprise is that spending has been lower, generics or whatever, that was not anticipated.

DR. CROSSON: I may not have been clear. No. That's a larger question about whether Part D is in trouble or is actually doing quite well, but what I thought I heard you and Jack saying was that -- maybe just Jack -- the reinsurance belt was most effective for short-term unpredictable losses, whereas the development --

MS. UCCELLO: It's the other way around.

DR. CROSSON: Okay. What did I say?

DR. MILLER: Corridor.

DR. CROSSON: I'm sorry. The risk corridor was more effective. Whereas, if you had a new cholesterol drug and virtually every male over the age of 45 was taking it

and it was high cost, that then the risk corridors would be more effective for that. Whereas, reinsurance -- or did I get it completely backwards? Help me.

DR. MILLER: Here's what I would have said, okay? And you guys see if I am following any of this along. What I heard Jay saying is you have set this up, and I am pretty sure it was Cori who said just because we want -- well, we want to have the defendant, you know, identified for the Court.

[Laughter.]

DR. MILLER: The corridors might be -- and, Cori, in all serious now, back to your comment, I think what you were saying is the corridors might play a role in which there is a short-term shock, and then -- and I realize there's many different ways, but just to say -- and so he then was asking do you see a pattern there that suggests short-term shocks or some other pattern. And what I would have said is, "No, I don't see a short-term shock kind of pattern," because I would have guessed more noise in the corridor if it's really about I didn't anticipate something in the market and it showed up versus what -- there's a little noise there at the beginning, and then it kind of

flattens out, and then year over year, you just get -- and then again -- well, I'll stop there.

MS. UCCELLO: And I'll continue.

DR. MILLER: Thank you.

[Laughter.]

MS. UCCELLO: Yes, that's -- I agree with you, and I think on the reinsurance side, maybe the evidence that backs up my statement is that the reinsurance payments have been increasing over time, and so it's a cumulative effect.

DR. HOADLEY: And, in fact, the -- I mean, here, you're showing the reconciliation part. But, if you showed the base thing, it would be a similar pattern. It's been high and getting higher and that's presumably reflecting something more about the overall pattern of high use that we would expect.

So, it's one thing to say what happens when a new drug comes in that year and it was too quick to anticipate. It's another thing to say a new drug comes in that's expensive for a small subset of people and it's going to continue to be there.

So, there's both the how do you react to it the

first year, which ultimately is what you sort of think of the risk corridor as being about, but in the long term, if there's more people that are up over the catastrophic cap continually over a period of time, that's going to be comparable to that sort of yellow line, saying high and growing higher.

MS. BUTO: I just -- I think this question is actually for Cori, but Rachel or Shinobu, and that is if we eliminated -- if Medicare were to eliminate the risk corridors altogether but MLR has gone into effect, essentially, would those bars kind of look the same? In other words, what they suggest is that the plan is having to pay back Medicare. Do we think that plans without a risk corridor and an MLR would be a little more close to that horizontal line and be more likely to hit it on the mark or be closer to it? I'm just wondering, because they do seem like those two things are very much aligned, given that they're paying the government back. MLR suggests that you might have to pay the government back if you haven't hit the medical loss correctly.

MS. UCCELLO: I'll just respond because you asked me, but this was actually my question to Rachel, and I

think that there are dissimilarities between the MLR and the risk corridor --

DR. SCHMIDT: It's only one-sided, for example.

MS. UCCELLO: -- getting different things, it's one-sided, but we care about this one side, but it will have -- it could have behavioral consequences for bidding that also would need to be considered. But, I mean, I think that's what you're going to be looking into a little bit more --

DR. SCHMIDT: Yeah. I think -- so, it doesn't -- if you get rid of the risk corridors and there is this, you know, the new cholesterol drug that everyone over 45 -- every man over 45 is taking, there isn't that protection anymore, right, if you get rid of the risk corridors, because the MLR would be one-sided. It's only recouping on the profit side.

We have a concern that I tried to say in the presentation. These things can be a little porous, you know, with the definitions of what qualifies as quality improving activities, for example. So, we're not sure how binding a constraint on profits MLR will ultimately be, but --

MS. UCCELLO: And, I think something that was brought up in the paper is that MLR can be criticized itself for not really being focused on the right thing. It's trying to squeeze the admin and the profit, but one way to increase your MLR is not to manage care as well and just to have higher costs. So, there's kind of some weird incentives here.

DR. MILLER: Shinobu, I keep remembering, when we had this conversation, you would always make a point about what the MLR applies to.

MS. SUZUKI: So, the denominator includes the reinsurance portion, which is that white box, 80 percent, and when you're allowed 15 percent on the basic benefit plus reinsurance, that's a much bigger profit margin than the five percent allowed for the basic portion of the benefit within the risk corridor.

MS. BUTO: So, it's not just -- so, we're actually going to count the government's 80 percent in computing the MLR, not just what the plan is at risk for.

DR. SCHMIDT: It's in both the numerator and denominator, yes.

MS. BUTO: Yeah. Hmm. That seems to be a

mistake. I don't know --

DR. MILLER: It seems to be something we should look at, and I think that's why every time we have this conversation, Shinobu goes, "Remember --"

[Laughter.]

DR. MILLER: So, I think you're on to something.

MR. HACKBARTH: Any other clarifying questions?

[No response.]

MR. HACKBARTH: Let me just get one other thing out on the table. So, some months ago, there was some controversy around the Affordable Care Act and the financial protections provided to insurers under the Affordable Care Act for some of the same broad policy reasons, trying to get people to play, et cetera. Could you just refresh our recollection on why some people thought, well, those are really problematic, but the ones in Part D are okay? How were they different?

DR. SCHMIDT: I'm not sure I have a good answer to that one. Do you happen to know, Jack?

DR. HOADLEY: I mean, both Cori and I have done testimony where that's essentially been the question. I mean, in a simple way, you can say the answer is that in

Part D, plans that pay back to the government, and the expectation by those who are worried about the ones in the Affordable Care Act is that the government will rescue, will pay back the plans. I mean, so, I think in the very short sort of simplistic way, that's been the concern.

MR. HACKBARTH: But the design is similar.

DR. HOADLEY: The design is similar. The biggest difference is that the Affordable Care Act ones phase out completely and these, while they -- as these guys showed -- they widened, and there is statutory authority built into the MMA to either further widen them or actually make them go away? Both?

DR. SCHMIDT: Yeah, as long as it's at least as wide, you could conceivably get rid of it.

DR. HOADLEY: They can do more. I mean, the law built in the opportunity to do more. CMS has not opted to do that. But, they are permanent in the sense of there's no phase-out created.

MR. HACKBARTH: I think we're ready to go to round two. Who wants to lead on round two? Jack.

DR. HOADLEY: So, it seems to me that a lot of this is driven by sort of thinking about the kinds of

questions we've already been talking about, of sort of where cost pressures come from and what's the best way to sort of design the program to address those pressures in a useful way.

You know, right now, the best guesses are that the cost pressures on Part D are going to come from specialty drugs, from expensive drugs, whether they are the Hepatitis C kind of example, which is a relatively small number of people at a very high price, or the potential coming cholesterol drug that could be also expensive, not at the same level as Hepatitis C, but with a much larger set of people, potentially. Obviously, lots of questions about the clinical judgments that will be made at that.

And, I mean, I think part of where I try to think about this is where is the burden in that cost? Where are the incentives to manage those costs? So, on the one hand, you've got some burden on the individual beneficiary, even in the current design. I mean, if you put that 80 percent, the white box figure, back up, there's still that five percent that the beneficiary is responsible for, so they are going to bear some of the burden, and that's -- I said at the last meeting, if we start doing some changes, we

might want to think about out-of-pocket maximums for Part D or otherwise messing around with that five percent.

But, we've sort of divided up the impact on the plan and the program in a particular way through this so that, as I said before, the 2014 experience in Hepatitis C seems to put most of the cost on the government through the reinsurance and doesn't put a lot of burden on the plans to manage.

And, so, I think, thinking through those trade-offs, where do we think that would -- and to me, it kind of comes back almost to our last session. It's what are the tools -- you know, then, we were talking about opioids and polypharmacy. Here, we might be talking about new drugs coming on the market. What are the tools -- clearly, the government doesn't have a lot of tools, although the government, because it has to do it indirectly through the plans, the government can't negotiate prices. The government can allow or disallow some of the management tools for utilization, and we might want to think about some of those.

But, if we are going to change these mechanisms to try to put -- if we think part of what this structure

creates is not a lot of incentive for a plan to manage a new Hepatitis C drug or a new cholesterol drug that will kick a lot of people into catastrophic coverage, do we want to change the risk rules so that there's more incentive on the plans to manage, but do the plans have the tools in a sort of stand-alone Part D environment to do that management.

MR. HACKBARTH: And, sort of the flip side of that is, so, take the Hep C drugs. A lot of that spending is going to be in the individual reinsurance, and, oh, by the way, there's a prohibition on the government negotiating with the insurers about the price of those drugs. So, the risk is shifted from the plan to the government and the government, by law, is prohibited from doing anything about it.

DR. HOADLEY: And, even if the burden was more on the plans, there's the question of whether some of the rules around formularies and management, so the kind of things you heard about in the private sector, where Express Scripts and some of the other PBMs came in and negotiated lower prices, could implement them right away, for good reasons, we don't necessarily allow plans -- or, we don't

allow plans to change their formularies in mid-year, so there's a lag before they could trade a more favorable formulary position. There are questions of what CMS would allow in terms of formulary treatment of these drugs and other kinds of things, all of which have some good reasons behind them. But, they'll intersect. So, the government can't do certain things, as you point out, like negotiate prices. The private plans can negotiate prices, but they have some hands tied in doing that.

And, so, I think the point is we should be thinking about these issues, and I've said before some thoughts on how we might do that. But, I think it's dangerous to do that in isolation of, okay, what's the second order effect on the beneficiary? What's the second order effect on the plans' tools to manage? And, do we make sure -- should we be looking at a package of things to say, okay, we want to do this here, but in turn, we either want to recognize that the plans' tools are limited, recognize that the government's tools are limited, change the limits on either side and think about how to do all those things in tandem.

MR. HACKBARTH: Round two. Cori.

MS. UCCELLO: So, every time we have discussed risk sharing in Part D, I have complained that risk corridors make no sense at this stage of the program. That's all theory. In the real world, I think I'm kind of waving the white flag now, notwithstanding what we find out about how the MLR shakes out. It just doesn't make sense to make changes to that now, given that the government is a net receiver of payments. It just doesn't make sense. So, I think we do need to focus more on kind of the reinsurance side along with some of these ideas Jack has about, well, tools plans have and those kinds of things. But, I think in the short term, that's where we need to be focusing.

MR. ARMSTRONG: Two very brief points. One, I just want to affirm Jay's point earlier. I always get Jack and Cori confused.

[Laughter.]

MR. ARMSTRONG: So, I understand that.

But, more seriously and not too specifically, and I'm repeating a point I've made before, drug spending in the Medicare program is a huge emerging problem. It's only going to get bigger. And, I think that the risk sharing in Part D is a component part of that, and I think there are

some real issues we've identified here. I'm not an expert. I can't speak like these guys can to some of these issues. But, I think at some point, we do need to just check to affirm that we're dedicating the limited resources of MedPAC and our staff on those variables that will have the biggest impact in the next decade on overall costs to the Medicare program of pharmaceuticals.

And, I haven't taken the time to kind of step back and just check on that, but I just would really encourage us to do that as we get ready to gear up and really dive into some of these specific questions.

DR. REDBERG: Just a comment, maybe. It's related to Scott's. And, picking up on what you said, but it does concern me that Medicare has this rapid increase in costs and reinsurance at the same time that Medicare can't negotiate prices, at the same time when there are a lot of very expensive drugs coming on the market that are priced really in ways that are inexplicable, I would say, at best, and certainly not related to any kind of benefit for Medicare beneficiaries, and clearly we're headed that way and that's a situation we need to really do something about quickly, because we're looking at billions of dollars for

unclear outcomes and, no market operating in Medicare right now, being very seriously at risk for those costs, and not just Hep C.

DR. COOMBS: I'd be interested in what the low-income subsidy looks like with and without risk corridors, if there's a difference, based on how often you hit the catastrophic, the sub-catastrophic, numbers, and what a more tailored approach might look like. You know, we've talked about getting rid of the risk corridors altogether, but what if there was a hybrid where you had a certain benchmark for LIS within a population and, you know, just looking at how proportionality makes a difference with combinations of non-LIS versus LIS.

DR. SCHMIDT: Let me make sure I understand, or maybe I can ask you to speak a little bit more. So, right now, I think it's on the order of 80 percent of the people who hit the catastrophic have LIS. So, are you asking to have kind of a different level at which their reinsurance would kick in, or what --

DR. COOMBS: What would happen if you had a different rule applying to both, in other words, risk corridors with LIS versus none with non-LIS.

DR. SCHMIDT: Well, the thing with the risk corridors, that's a plan's overall spending --

DR. COOMBS: Right. Correct.

DR. SCHMIDT: -- for all enrollees.

DR. COOMBS: Right.

DR. SCHMIDT: So, you're saying --

DR. COOMBS: So, for instance, with the Hepatitis C, at the rate of $84,000 or how much ever for the treatment plan, you're going to hit catastrophic in non-LIS populations, presumably. And, with the literature from ID saying we want Baby Boomers to be tested and the estimation from the house of ID saying that somewhere between 50 and 75 percent of people who are Hep C positive don't know that they're Hep C positive, and whatever percentage of that that has chronic active Hepatitis.

So, I'm being futuristic and thinking that it's not just the LIS that's going to drive costs in the future. There will be this new group that's not necessarily LIS, and so how do we look at changing the paradigm in the future, or looking at this new cohort that's not necessarily LIS and what they look like without risk corridors versus LIS going forward.

DR. MILLER: So, I think we're going to have to take what you said and think about it and come back. But, I want to make sure that I at least carry out of the room what you were asking. So, in the end, what I took away from it was you might want to think about a different corridor, or you're asking whether it makes sense to have a different corridor structure -- I'm leaving reinsurance out of it for just a half-a-second -- for different populations. Okay. I think we can think about that and -- I wouldn't want to try and take that on the fly, although we could ask Cori to do it. But, I want to make sure I followed your question.

MR. HACKBARTH: Is there a relationship between a plan's enrollment of LIS beneficiaries and its likelihood to exceed the risk corridor?

DR. SCHMIDT: We've just recently gotten data to be able to answer that, but I don't have that analysis completed, but I can try and do that and come back to you.

MR. HACKBARTH: Okay.

DR. COOMBS: And I just have an important point, Glenn, and that's where we're going. The other thing I wanted to say is in terms of medical loss ratios, I don't

have a whole lot of hope in medical loss ratios and how they're done. We had -- as you know, in Massachusetts, we had that as a benchmark many years ago and still there are ways around it, and I think that medical loss ratio, the way it's calculated, gives us a little leeway into how we can change the paradigm for Medicare.

DR. HOADLEY: Yeah, I wanted to follow up on the LIS thing. I mean, clearly, we need to think about how this plays out, and the kind of data you're talking about would help on that.

There are also some policy levers, however, we could think about on the LIS side that sort of otherwise don't have to do with this, but as we're talking about how they intersect. So, some of the ways you get that lumpiness of LIS has to do with basic versus enhanced plans. But, some of it has to do with the things that sponsors have been allowed to do in terms -- that have encouraged them, in a sense, to segregate their LIS enrollees into one plan as opposed to another. And, so, some -- and some of those CMS has addressed in rules and then not gone forward with. But, we might want to think about some of those policies to lessen the amount of

complete isolation of LIS in certain plans and not, because if you have a more mixed plan, at least, it might change some of those bidding incentives that Rachel and Shinobu have talked about.

DR. CHRISTIANSON: Yeah, I was going to comment on that, too, Jack. I think one of the things we haven't talked about much today, but we did previously, is the sort of bidding incentives and how they might relate to what we're seeing in that graph that everybody's commenting about. I think that's important to keep in mind.

But, I also think one of the things that this chapter really does, and this work does, that's very important is it focuses attention on sort of the full picture in terms of the Part D program instead of what I think is kind of the naive focus on just the bid prices and looking at the bid prices and saying, here's how the program is functioning. And, I think, just by having this chapter, laying all of this out and saying to people, look, it's not just the bid prices. You have to look at the whole picture, and here's how it relates, is a really important thing that we can bring to the policy discussion.

I thought the chapter was just fabulous, by the

way. It was just great. But, that's me. I wanted to be an actuary.

[Laughter.]

DR. CHRISTIANSON: In high school -- and you'll appreciate the irony of this -- the local medical society gave me a scholarship to go to college to study to be an actuary.

[Laughter.]

MR. HACKBARTH: [Off microphone.]

DR. CHRISTIANSON: Well, I didn't. Actually, I didn't, because I found out in the course of my study that I didn't have a good enough personality to be an actuary --

[Laughter.]

DR. CHRISTIANSON: -- so I became a health economist instead. It's an old joke, Cori. I know you've heard it before.

DR. SAMITT: So in our last session, we talked quite a bit about learning lessons from best practices or from other sectors in the industry, and, you know, what I haven't heard us talk about -- and I'd be curious to get other folks' perspective on it -- is the fact that, you know, I'm not sure why we're so worried about risk bearing

by these plans, especially because these same plans, many of the MAPD plans and the PDP plans, already do bear global drug risk in the commercial sector. So they already do have to take accountability and responsibility for under 65 in managing full risk without reinsurance for the most part from Medicare or some other body other than their own independent reinsurance. They already experience this whole world for a large subset of their patients.

So I don't know to what degree we've actually looked into the commercial world, the private world, to really understand whether there are any lessons learned here from a risk-sharing, risk management perspective for drugs, and taking some of those lessons and making them applicable to some alternatives here in Part D.

DR. CROSSON: So in thinking about narrowing the work, would it be reasonable to say -- I did listen to Cori.

DR. SAMITT: Or Jack.

DR. CROSSON: Yeah, I know. I listened to both, but with respect to taking a look at the risk corridors, maybe not, taking a look at reinsurance, maybe that's what we should be doing, it seems to me that it might be helpful

to get more granular, if that's possible, about what's actually going on with respect to that spike in reinsurance payments. And I don't know what I'm saying, whether I'm talking about the clinical issues, the emergence and rate of emergence of new drugs, or some of the incentive dynamics, or all of those things. But it seems to me that if that's where we want to go and that's where we want to focus, maybe if we understand at a more granular level what's actually going on there, it would tend to point to some solutions.

MR. HACKBARTH: Round 2 comments [off microphone].

MS. BUTO: So I don't know at what point we think about making recommendations, and maybe -- this feels like it's too soon, but at least on the area of reinsurance, it seems to me we're moving toward a set of recommendations, or at least a direction that we -- at least my sense is that we think we might want to go, because if you relate this piece of work to the work that you all have done on LIS and generic drugs, I think the same issue -- there is a related issue, which is, if you've got Medicare bearing 80 percent of the risk on reinsurance, then it's a lot less

likely that the plan is going to put pressure during the coverage gap in other places on trying to substitute generics for brand-name drugs.

So it just strikes me that we are probably moving in the direction of trying to move the plan into more of that risk on the reinsurance side. I could be premature in saying this, but if we're doing that, I'm just wondering when would we do that. In the next go-round next year? Or would we just basically talk about it this year and then take it up in more detail next year?

DR. SCHMIDT: Right. I think the plan was to kind of introduce the topic notionally -- and go ahead, you can jump in, Mark -- and then next year come back to you and, you know, as we get feedback from you, to kind of develop some policy options to take forward.

DR. MILLER: And the only thing I was going to say is, you know, this is not atypical for this part of the cycle. We're putting up a lot of topics, as you think about them, that are kind of open-ended, and, hey, we did some data analysis, what do you think about this? Trying to draw you out. We write it up in the June report. This will bring out other actors in the environment who will

come in and tell us what they think about these ideas. Then we'll come back into our regular cycle in the fall and start coming through this again. And if your opinions start to gel, then we start to move into recommendations. But we're not trying to do this before the June report.

MR. THOMAS: First, a clarifying question. Do we look at the margin on this, these products, with the insurers?

DR. SCHMIDT: We took a tentative look at it from bid information, but the data in that were not -- were before reconciliation, so I didn't bring that to you because we need to use the reconciled data to do that. But that's another piece of data work that we hope to develop further and come back.

MR. THOMAS: So just building on Craig's point, I kind of sit here and am curious as to why we have reinsurance at all, given the size of the program. We can understand in the beginning when we wanted to get people interested and in the program. But today, given the size of the insurers that have this and the scale of this program, to me it just doesn't seem like it would make a lot of sense that the Medicare program would be taking any

of this risk. I mean, I can't imagine that there's going to be folks that back out of this program significantly given that it has been so successful.

So I think as part of the analysis we ought to be looking at what do the margins look like, do we really think there's risk that people would pull out of the reinsurance goes away? Because my sense is that that was important early on, but it's probably not as important today. It would be interesting to just kind of ask ourselves that question as we go through the process.

MR. HACKBARTH: Okay. Anybody else?

DR. HOADLEY: Just a follow-up to that and Craig's comment. I mean, I think Warner's point is well taken. I think it's -- I generally tend to agree with it. The difference in sort of looking at private sector experience is the stand-alone drug plans don't really have a private sector, and that's the kind of point Mark has made a couple of times. There's not really a private sector equivalent to those. So, I mean, that's the sort of thing you always have to keep in the corner of your mind. That is a different kind of product.

But to Warner's point, it's now ten years in.

They are the big companies. They seem very into doing it. You know, it works in the market. You know, risk adjust still -- you know, the more we drop some of the other things, we have to keep our eye on risk adjustment. That's certainly also true. And we have to think about that, you know, in deciding which of these things, to sort of Kathy's point, as we try to gel towards a recommendation, what's the right combination and what are its second-order effects so we can kind of be ready to do it right.

MR. HACKBARTH: This will provide further evidence that I am not an actuary. Is risk adjustment easier or more difficult in Part D versus Medicare Advantage, you know, when you're dealing with a narrower group of expenditures versus full range of services? Is it maybe lumpier in Part D, you know, more variation at the -- Cori's laughing at me.

DR. SCHMIDT: Do you mean overall variation in spending or the development of the -- I mean, a complication that CMS has in developing the risk adjusters is that there is this individual reinsurance piece that Medicare's paying, so they have to estimate plan liability.

MR. HACKBARTH: Right.

DR. SCHMIDT: But in the text box, we tried to get at the question of whether there's a different coefficient of variation underlying variability.

MR. HACKBARTH: Yeah, right. That kind of stuff is what --

DR. SCHMIDT: And we found that, you know, the overall coefficient of variation for A-B spending has been pretty constant over time and is wider than it was for Part D at the start of the program. But now the overall liability of Part D has gotten to be the same. We'll probably come back with some further analysis at a future point that's showing that the plan liability, however, may not have the same degree of variability as the total spend because of the individual reinsurance.

MR. HACKBARTH: Right, right. Well, I'm sort of going back to the original point from Slide 3 about one of the strongest reasons for the individual reinsurance is to make sure that if the risk adjustment system isn't good enough to prevent skimming, that this is sort of a backup on that. And that's why I'm -- and, of course, in MA we feel like the risk adjustment is good enough -- not perfect, but good enough to prevent -- along with market

regulations, good enough to prevent wholesale skimming. And if the rationale for individual reinsurance is to protect against skimming, again, I'm trying to think about how good is the risk adjustment here versus MA. It seems to me that's sort of a central question. I haven't heard any reason to think that -- to back up the case that, oh, we need individual reinsurance here, but we don't need it in MA. I have yet to see that evidence.

DR. HOADLEY: In fact --

DR. MILLER: And the thing I was trying to remember was -- and this will cut both ways. I thought the explanatory power of the risk models in D were higher, and you said easier, but my mind went to which side is the explanatory power higher. But I think the other caveat that has to follow right on to that is they're not explaining the whole risk in that model, right? They're not -- right, that's --

MR. HACKBARTH: As the reinsurance [off microphone].

DR. MILLER: Yeah, so I think we're back to I'm not sure.

DR. HOADLEY: But individuals -- I mean,

individuals' drug use in general is more stable year to year than -- even if total spending is sort of what they show in their text box, individual -- I mean, that's more a matter of, okay, for every person that gets more sick on the A-B kind of expenses, somebody else doesn't; whereas, in D it's a lot more the same people having similar levels. And you do have the shocks to the system with new drugs. So that's a sense in which, you know, risk adjustment at least is no harder in D than in A-B.

MS. UCCELLO: But you could argue that it's more important when spending is more predictable --

DR. HOADLEY: Yea.

MS. UCCELLO: -- and somebody knows more and the insurer might be able to know more, then the risk adjustment is even more important because you care more about the predictable costs as opposed to the random costs.

[Comments off microphone.]

MR. HACKBARTH: Okay. Next is measure low-value care.

[Pause.]

MR. WINTER: Good afternoon. I want to begin first by thanking John Richardson for his help with this

project as well as Aaron Schwartz and Dr. J. Michael McWilliams of Harvard Medical School, who helped with our analysis, as I'll talk about later.

We'll start by talking about our motivation for exploring this issue. There has been increased interest in recent years in measuring and reducing the use of low-value services. There is a growing literature that explores this topic, including the studies cited here as well as several others.

For example, analyses sponsored by the Commission found higher-than-expected rates of repeat diagnostic testing among Medicare beneficiaries.

In addition, practitioners are making efforts to identify and reduce low-value services through the Choosing Wisely campaign, an initiative of the American Board of Internal Medicine Foundation.

Thus far, over 60 medical specialty societies have identified more than 300 tests and procedures that are often overused.

As part of our recommendation in June 2012 on redesigning the Medicare benefit, the Commission supported value-based insurance design in which CMS could alter cost

sharing based on evidence of the value of service. Under this approach, cost sharing would encourage beneficiaries to use high-value services and discourage the use of low-value services.

And finally, last year, we measured potentially inappropriate imaging services, such as MRI scans for low back pain using Medicare claims data, and published the results in our June report.

For today's presentation, I will be talking about the development of 6 claims-based measures of low-value care by a team of researchers. With their help, we applied their measures to 2012 Medicare claims data. I will describe the results of our analysis of these measures and then finally describe some potential next steps.

So, first, it's important to define what we mean by low-value care. Researchers define low-value care as services with little or no clinical benefit or when the risk of harm from a service outweighs its potential benefit.

Another term for this type of care is "overuse." Low-value care is a concern for two reasons. First, it increases health care spending, and second, it has the

potential to harm patients, both directly by exposing them to the risks of injury from the service itself and indirectly when the initial service leads to a cascade of additional tests and procedures that contain risks but provide little or no benefit.

A group of researchers that included two physicians developed 26 measures of low-value care and published their findings last year in JAMA Internal Medicine. Sixteen of their measures were based on Choosing Wisely guidelines. Other measures came from the U.S. Preventive Services Task Force recommendations, the medical literature, and other sources.

The authors applied these measures to Medicare claims data from 2009. They developed two versions of each measure, a broader one with higher sensitivity and a narrower one with higher specificity.

Increasing the sensitivity of a measure captures more potentially inappropriate use, but is also more likely to misclassify some appropriate use as inappropriate. Increasing a measure's specificity means that it is less likely to misclassify appropriate use as inappropriate, but it is more likely to miss some instances of inappropriate

use.

To explain these concepts, will look at some examples of specific measures, and the full list of measures is in your mailing paper.

The first measure on the slide detects inappropriate back imaging for patients with a nonspecific low-back pain. The broader version of this measure includes all patients who received imaging for low back pain and therefore captures more inappropriate use but also some appropriate use.

The narrower version of this measure excludes certain diagnoses, such as cancer and trauma, and is limited to imaging that is provided within the first six weeks of the diagnosis of low back pain. Although the narrower version identifies fewer cases of inappropriate imaging, it is less likely to misclassify appropriate use as inappropriate.

The second measure identifies inappropriate use of colon cancer screening for older patients. The broader version of this measure includes all beneficiaries older than age 75, and the narrower version is limited to beneficiaries older than age 85 with no history of colon

cancer.

The third measure detects inappropriate use of head imaging for an uncomplicated headache. The broader version includes CT or MRI imaging of the head with a diagnosis of headache that is not a thunderclap or post-traumatic headache.

The narrower version is limited to beneficiaries who don't have a diagnosis on the claim that warrants imaging, such as epilepsy or cancer.

We contracted with the authors of the JAMA Internal Medicine article to obtain their measures and the algorithms used to calculate them. So here are some differences between our analysis and theirs.

We used a later year of claims data than they did, 2012 versus 2009; a larger sample size, 100 percent of beneficiaries versus 5 percent; and a larger population. We included both aged and disabled beneficiaries, whereas the authors of the study only included aged beneficiaries.

In addition, the authors made small changes to some of the measure specifications after publication of the article, and we incorporated these changes in our analysis.

So here are the aggregate results from our

analysis of all 26 measures. Based on the broader versions of the measures, there were 65 instances of low-value care per 100 beneficiaries in 2012, and 37 percent of beneficiaries received at least one low-value service.

Medicare spending for these services was about $6 billion, and that includes beneficiary cost sharing. Based on the narrower versions of each measure, there were 28 instances of low-value care per 100 beneficiaries, and 21 percent of beneficiaries received at least one low-value service in 2012. Total Medicare spending for these services was about $2 billion.

We also grouped the measures into six larger clinical categories, using the same categories as the authors of the article. We found that imaging and cancer screening measures accounted for about 70 percent of the volume of low-value care in 2012, under both the broader and narrower versions of the measures.

However, cardiovascular testing and procedures and imaging accounted for most of the spending on low-value care, between 60 percent and 72 percent, depending on the version of the measures.

So to take an example, based on the broader

measures, the cardiovascular testing and procedures category accounted for 9 percent of the total volume of low-value care but 56 percent of spending on low-value care. Although these services occur less frequently than other low-value services, they receive much higher payment rates per service.

Here are results for some of the individual measures. Results for all of the individual measures are in your paper.

The first row on the slide shows back imaging for patients with nonspecific low back pain. Based on the broader version of measure, the number of cases per 100 patients in 2012 was 12.0 and spending was $224 million. Based on narrower version, number of cases per 100 patients was 3.6, and spending was $67 million.

Looking at the second measure on the slide, colon cancer screening, the number of cases per 100 patients ranged from 8.7 under the broader version to 0.4 under the narrower version.

And if we look at the third measure, head imaging for uncomplicated headache, there was less variation in the number of cases per 100 patients, 3.8 to 2.6. These

results show that the volume of low-value care that we detected can vary substantially based on the measures' clinical specifications. For other measures, however, ere is much less variation between the broader and narrower versions.

I also want to point out that the measures on this slide account for a relatively high share of low-value care. There are other measures that we looked at that account for very small shares.

Our results may understate the volume and spending on low-value care, and thus, they represent a conservative estimate of the actual amount of low-value services. This is for following reasons. First, there are limited number of measures of low-value care that use claims data.

As I noted earlier, this project used 26 measures, while the specialty societies in the Choosing Wisely campaign have identified over 300 tests and procedures that are often overused.

It can be challenging to identify low-value care with claims data because claims may not have enough clinical detail to distinguish appropriate use from

inappropriate use. Thus, we are unable to measure the full extent of low-value care with claims data.

In addition, our spending estimates for the 26 measures probably understate actual spending on low-value care because they don't include downstream services that may result from the initial low-value service. For example, if an imaging study has incidental findings, the patient may have several follow-up tests and procedures to explore these findings.

So we include spending on the initial imaging study but not spending for any follow-up tests or procedures.

Before I conclude, here are some potential next steps for your discussion. First, we or CMS could track and publish rates of low-value care on a regular basis. This could highlight the prevalence of low-value care for policymakers and the general public.

Second, CMS could alter Medicare's coverage and payment rules to be consistent with evidence of low-value care.

Third, Medicare could increase beneficiary cost sharing for low-value services, which is the concept I mentioned earlier.

This concludes my presentation, and I'd be happy to take any questions.

MR. HACKBARTH: Well done.

So Round 1 clarifying questions beginning with Herb.

MR. KUHN: Quick question on Slide 9, and I'm just curious about the first dot point when you put it in these categories. You mapped these to the BETOS categories. Is that what occurred here?

MR. WINTER: The authors of the JAMA Internal Medicine article created their own categories. So imaging would include things like back imaging for low back pain, CT scans for sinusitis, cancer screening measures including the colon cancer screening, cervical cancer screening, PSA testing, those sorts of things. And the full list of -- if you look at the appendix to your paper, it tells you -- it shows you which measures are in which categories.

MR. KUHN: Okay. Thank you.

And then on the image and cancer screening measures, obviously, you said that counted for 70 percent of the volume here of low-value care. Does that correlate also with where we're seeing the highest growth in spending

of the Medicare program?

So imaging is growing very fast. So we're seeing -- would this be more correlated -- are those two correlated at all, or have we looked at that yet?

MR. WINTER: That is a good question. I have not looked at that, although it is correct that imaging has been growing rapidly over the last decade or so. Within the physician fee schedule, the volume has plateaued or begun to decline a little bit, but in the outpatient department, as you know, it's been still increasing pretty rapidly. So that's something we could look at going forward.

MR. KUHN: All right. Thanks.

DR. COOMBS: So in the reading material on page 16 and page 17, I like the way you display that and combining that with Slide 10. For the cardiac services, the volume itself, you demonstrated that it's lower. The cost is higher, but what would be interesting is if you took the total bottom number, volume of the total bottom number cost and showed to what degree, to what extent are these true outliers within their total denominator. I don't know if that's possible, but it sounds like it is

possible, going from -- say, for instance, an example would be using the broader version definition of imaging for low back pain, total cost for low back pain, and what percentage outliers if you do by volume or what percentage increase in spending is attributable to that entity in and of itself.

And the reason why I asked that question is because later on, it might prioritize services that are true outliers based on the volume that is normally prevalent for true indications.

I don't know if that data exists, and I'm asking you if it does.

MR. WINTER: So are you asking for measures that are outliers; that is, they have high volume or high spending, like imaging for low back pain, for example, what percent of the imaging category does it account for? Is that what you mean by denominator?

DR. COOMBS: Yes.

MR. WINTER: Okay. Yeah, we can do that. We haven't done it for that analysis. We have the numbers to do that, and it would account -- I can tell you right now it accounts for a lot of the total imaging category is in

that first measure on the slide, the low back pain measure.

DR. REDBERG: Great job, Ariel. It was a really interesting chapter and work.

Certainly, this area of low-value care seems like a win-win because we're spending a lot of money, and people are being harmed. So we could be spending less money, and people would be better off. That seems pretty good combination.

I just wanted to ask in particular about the PSA screening. I suspect maybe you took over 75 because that's what the authors did in their 2009 data, but in between 2009 and 2012, when you analyzed the task force actually revised and said no PSA screening of any age was not beneficial. So I'm just wondering whether we should revise that to PSA screening of any age.

MR. WINTER: You're correct. We took the definite -- their measure, which was from 2009, and they used the information or the recommendations that were available in 2009, and I guess the PSA measure was updated after that.

DR. REDBERG: Yeah.

MR. WINTER: We can talk to them about revisiting

that, or we can think about doing it ourselves, looking at all PSA testing. It doesn't matter -- the age doesn't matter anymore.

DR. REDBERG: Just to add on -- and you did note that, but I would just note that means the cost of the test is kind of minuscule compared to all the additional treatment that Medicare pays for based on those unnecessary tests, and so that's a lot of chemotherapy, radiation therapy, proton beam therapy. I mean, that's huge, and to look at that where clearly the test score has stated the harms outweigh the benefits.

I have more comments that I'll save for Round 2.

MR. WINTER: And just to follow up on that, in the article by Schwartz that we talked about, they do cite a different study which says that the total cost associated with PSA testing, when you include all the downstream services -- the cost of the test itself is only 2 percent of the total spending that is associated with the test. That's probably a very extreme example, but it does illustrate the upper end of the range.

DR. REDBERG: Maybe not that extreme.

MR. HACKBARTH: When we publish this, it seems

like the point about this not capturing downstream costs and the fact that this is just 26 services, not the 300 low-value services identified by specialty -- those points, they ought to be like flashing in a new report feature that we have lights that go off, because if you miss those points, you look at this and say, "Boy, these are small numbers relative to the size of the Medicare program." Making those points very prominent, I think is important.

Further clarifying questions? Jack.

DR. HOADLEY: Okay. My question was right along the lines we were just talking about. You didn't use it on this slide, but in the chapter, you talked about the share of all Medicare spending that these dollars on Slide 8 represent, and I think it was 2 percent on the bigger one or something like that.

MR. WINTER: Right. 1.7 percent.

DR. HOADLEY: 1.7 percent. And my follow-up to that was, in a sense, the question we've just been talking about is what we don't know, and obviously what maybe we could know in some further analysis is how much total spending this could involve if you sort of did all the caveats on Slide 11. Obviously, you can't do that, except

to put the caveats in flashing lights.

Then to Alice's kind of point, it seemed like it also might be interesting whether in some of these specific areas that do the same kind of percent -- and you were alluding that on imaging, what percent of these particular imaging numbers out of all imaging, and that would help us bracket, again, with the same flashing lights, that it doesn't necessarily cover all of the downstream costs, et cetera.

MR. WINTER: Yeah. Those are both good points.

I just want to caution us about trying to identify the full downstream cost associated with an initial service will be quite difficult, as you can imagine. We can cite the literature, like the study that talks about the total cost associated with the PSA test. There is also literature that looks at the downstream costs associated with an MRI scan for low back pain that looks at the downstream surgical and procedure cost. So we can look at the literature and see what's already been researched.

MR. HACKBARTH: Okay. Clarification questions? Dave.

DR. NERENZ: Just a semantic question. I guess

we could go to Slide 4, although it's right in the title.

A couple of bullet points suggest that "low value" is actually kind of a kind and gentle term. The real term is "no value." But the question is, Are there elements of this discussion where the proper term really is "no value" or even negative value, harmful? I think it matters because the policy options, I think might be chosen differently if we're talking about some small positive value, which is my sense of what the word "low" means, and literally no. In my own mind, I would take those in different directions.

MR. WINTER: Right. I think because we're using definitions that are from the literature and specifically from this paper, and I think you want to be a little bit cautious when you're defining or measuring these services just with claims data because there might be diagnoses that are not on a claim or that are not in the patient's history. There might be symptoms that are not reported in a claim that could qualify it as recommended or having some value.

But there are also services like the Preventive Services Task Force that said above this age, colorectal

cancer screening provides no benefit. There's higher moderate certainty it provides no benefit.

What you're saying could apply for certain services, but perhaps not for others that we've looked at.

DR. NERENZ: Right, and I wasn't suggesting that we change the term across -- what I'm just wondering, if for definable subsets, it would actually be appropriate of it to think as no value. Okay.

MR. HACKBARTH: Clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Round two. Alice.

DR. COOMBS: I just wanted to start with something, and that has to do with this specific task forces and the various specialties who take a stand on value and choosing wisely. And, recently, actually, last week, a New England Journal article came out regarding early goal-directed therapy for sepsis management, and it has been the 11th Commandment in sepsis management to go early goal-directed therapy. This article came out and there is a cacophony of sounds from all areas of ICU across the country about not being aggressive, being equivalent to the aggressive measures of putting lines in and treating

people aggressively.

And, so, with the advent of this article, we're right now at an impasse between the specialty societies and what the literature has said, and it takes probably about, I'm going to say probably another two to three years before literature catches up with practice. We saw this with activated protein C in sepsis management, a very extraordinarily expensive therapy, and it actually happens that within two to three years, you don't see activated protein C for sepsis management any more.

So, I wanted to speak specifically to the prostate issue and the PSA. There is a group and a population that may be more at risk, and the task force comes out with a strong statement regarding PSA. They came out with breast screening. We have to be cognizant, there's a large proportion of individuals -- a black male who comes in at 45 years old who's got a positive family history and may or may not have symptoms, people will argue that that person needs to be screened because he will die of prostate cancer quicker than a white male. And, it is said that if a white male gets diagnosed with prostate cancer, he is going to die of anything else but the

prostate cancer.

So, I think that it takes a while before the practice of medicine actually catches up with some of the recommendations. But, even in that, before we say it's a no-value service, realize that if you had proportionate X population, 25 percent of the population between blacks and Latinos that may be at increased risk of death from prostate cancer, you would say, before I make a global no-value statement, if it's valuable in one out of four patients, then you might retract that and say, let me give a narrower -- and I like the fact that we did the narrow -- according to the article, you might do a narrower definition in terms of specificity, the high sensitivity versus the high specificity.

And, that's all my point is, if we go forward with policy or go forward with recommendations, to bear that in mind.

And, each one of the categories, with the exception -- I agree with the imaging, because, you know, I had experience a few years ago where a patient came into the ICU, had 27 CTPA grams for rule out pulmonary embolism and one radiologist says, the buck stops here. We're not

doing this anymore. I mean, that's extraordinarily expensive, plus it exposes the patient to radiation.

So, I agree with Rita that there's a lot of therapy that's done that's harmful. But, let's not forget that when you have a proportion that's pretty significant that benefits from a certain service, you have to be very careful before we say it's no value or low value. To that entity, it might be valuable.

DR. NERENZ: Just to follow up on that, if I could, I think I agree with you, although it would seem like you could say, well, it's no value in this population, but it might be of some value in that population, rather than trying to force yourself to say it's got the same label everywhere.

MR. HACKBARTH: Part of the challenge here, using claims-based analysis, as I understand it is, the claims information won't always allow you to discriminate between the population where it might be clinically appropriate and the one that isn't, because there's no clinical information. I know I'm not telling you anything new here.

Let me ask you this, Alice. To the extent that this relied on the choosing wisely recommendations which

were developed by specialty societies, it seems to me that that also adds an element of conservatism in this. I would think that specialty societies, to some degree, they're political organizations and they have constituencies within them that need to be satisfied and addressed. I would think that they are not necessarily the boldest in terms of saying, oh, this is low-value services. These are low-value services within our specialty.

So, when a specialty society is saying, this is low value in our specialty, it's probably way out there on the continuum. Is that a fair guess, Rita?

DR. REDBERG: [Off microphone.] A very fair statement.

MR. HACKBARTH: Yeah. So, this is, in that sense, a very conservative measure.

Rita.

DR. REDBERG: Continuing on these fair statements, because cancer screening was such a big pot, I just want to note that I think it's going to get even bigger, because, as I think everyone here knows, CMS recently approved -- added another cancer screening benefit, lung cancer screening, which had, I think, a

fairly unusual history in that the U.S. Preventive Services Task Force gave it a Grade B recommendation on the basis of the National Lung Screening Trial. But, the Medicare Evidence Development Coverage Advisory Committee, which I chair, met last April -- so, I don't vote as the Chair, but the Committee voted overwhelmingly that the harms exceeded the benefits for lung cancer screening in the Medicare beneficiaries after reviewing the data very carefully.

And, I'll just, for example, 96 percent of the nodules identified were false positives, and so that really amplifies the harms, because when you have a false positive -- and they didn't have quality of life data from the National Lung Screening Trial, so we don't know, but I can't imagine that being told that you might or might not have lung cancer after a screening CT, people, I think, have a decrement in quality of life, but they also have more procedures and those are procedures at significant risk, like lung nodule biopsies or thoracotomies. And, the rates of surgical procedures were much lower in the National Lung Screening Trial than they are in real world practice, both in terms of complications and just in terms of rates. And, so, that was why the Committee, among other

things, like there's a lot of variability, it's very difficult to read lung CT scans, very hard to read those nodules.

If you don't stick to the low-dose protocol, there were estimates from radiologists that the chance of getting cancer from the actual CTs was greater than the chance of getting cancer from your history of smoking.

And, so, I would suspect that lung cancer screening is going to be in this low-value care for Medicare beneficiaries, certainly, based on the -- and that is just about to start, and certainly there was a lot of concern about the harms from that screening test.

MR. HACKBARTH: Okay, round two. Scott.

MR. ARMSTRONG: So, briefly, I just would like to comment on this topic. I benefit from being unencumbered by the clinical evidence that Rita knows, but I just would endorse strongly the merits of advancing this evaluation and MedPAC's attention to this.

Frankly, the use of value-based insurance design is old news. We've been doing this for a long time. The evaluation of the impact on the Medicare program is, as we just acknowledged, very conservative, which I think it

should be. And, this whole argument that this is not just about getting control over investments that we can't afford in the future, but this is actually avoiding harm to patients. It is an incredibly powerful argument. I just wonder why we are so slow. I mean, what is it that's taking us so long to roll out the kind of proposals that we're talking about here?

And, so, that's the point of view I'm going to bring into the work that we have in front of us and I'm very enthusiastic that we're taking this on.

DR. HOADLEY: So, I also like this work a lot, and I think it's real promising. I can imagine a number of ways to extend analytically. I mean, you could look at geographic variations. You could look at provider-level kinds of things and just go different ways to try to see -- to understand better what's going on.

But, I also tried to think -- and I could also imagine drug data, thinking about drugs that we know to be of low value, and it sort of ties back to the polypharmacy discussion and other kinds of things.

But, I also tried to think a little bit about, so, how you might eventually address this from a policy

perspective, and I could imagine measures that ranged from, ultimately, making a different coverage decision and just say some of these things aren't eligible for coverage, to something that involved some kind of prior authorization or screening, and I know we've been down the route in some of the imaging areas with prior authorization and in the fee-for-service world it can be complicated, and prior authorization is always complicated in terms of doing it in a fair way, to profiling and ratings and publicizing sort of rates of use at a provider level or something to try to help to amplify it more as a point of public discussion, but, obviously, would have a less direct effect on changing behavior.

But, it seems like at some point over time, we should -- and I probably haven't thought of several other options -- begin to think about sort of what do you then do and what are the measures that could allow you to reduce these levels of use.

MS. BUTO: Yeah, I want to totally agree with Jack. I think the issue that we can tackle next is -- the issues we can tackle next are how might you use this information to revisit coverage? How do you

institutionalize this kind of review? So, is it MedPAC that does 100 percent claims data analysis every so many years? Is it Cori? Is it AHRQ? Whoever it is, there ought to be some way to make this a more regularized part of the Medicare program.

And then, I agree. I think prior authorization is one where people have given up. But, it seems to me that is one of the areas, one of the tools that is used occasionally, and only by statute, in the Medicare program. But, where we clearly see low-value care, it's at least one way to look at the care without making an all or nothing decision that we never cover this. I think Medicare is always nervous about that, because there is somebody out there who may meet the criterion, but who actually would benefit from whatever it is. So, prior auth is definitely one thing to look at.

But, I would also say, I think we have to look at the beneficiary, where generations of beneficiaries now getting much more used to dealing with complex information, information on the Internet. They would -- I think there is a hunger for this kind of information, and again, I think it's a matter of how do you get it out to them in a

way that they will actually receive it and take it in and do something with it.

MR. HACKBARTH: Just to pick up on Kathy and Jack's, so another approach to potentially reduce the provision of low-value services is bundled payment of various types. And, I wonder whether there's analysis that we can do there.

For example, are there some low-value services that are outside bundles, and we could look at the rate of use there versus services that are incorporated in a Medicare bundle, for example, the inpatient DRG system? I guess, now that I say that, we won't -- if it's in a bundled payment, we wouldn't necessarily have the information about the rate at which the services are used.

MR. WINTER: Well, you probably -- you would if there's a physician claim involved --

MR. HACKBARTH: Well, that's true. Right.

MR. WINTER: But, most of these, just as an aside, most of these are outpatient services. There are only a couple that are predominately performed --

MR. HACKBARTH: Yeah.

MR. WINTER: -- on an inpatient basis.

MR. HACKBARTH: Yeah. Well, anyhow, you get the point. Jon and I were talking about the other day and the standard of whether a service is appropriate or not, it used to be the finding that high cost sharing reduced utilization but did not really significantly alter the proportion of appropriate versus inappropriate utilization. I think at one point, Joe Newhouse had a similar finding within HMOs. Utilization was lower, on average, but the mix of appropriate versus inappropriate was not significantly different in his analysis.

All those studies, the ones that I know of, are quite old now, and I wonder whether there's some way to sort of update that analysis. As incentives are changed, do we, in fact, find less use of low-value services than in unconstrained fee-for-service?

So, other round two. Bill, and then Mary and Jay.

DR. HALL: Well, I really like this analysis. I think we may be on the brink of -- to have some optimism about the dissemination of these kinds of guidelines to inform care. There now, over the last five or six years, is a whole series of studies that have used Medicare claims

data and then merged these data with lots of other data sets, such as, for instance, in older people, functional state in the hospital, at home, things that are very, very important. And, this is all quite relatively new.

And, then, virtually all societies in medicine now have put out these Choose Wisely guidelines, but we don't share them very much among ourselves. For example, I was involved in the 20 that the American Geriatric Society put forward, such things that we talked about today as how to deal with polypharmacy, for example. But, I don't think we disseminate them very well, so a little experiment that we tried was to say, in our society, which is a very small group of physicians, relatively speaking, rather than just send our guidelines out to everybody else, why don't we take everybody else's guidelines and say, how do they apply to us? And, it was an absolute revelation, embarrassing kind of revelation for me. So, we don't mine that database very well.

So, now that we have these data and there's going to be a lot more of this, I think the thing you were getting at, Kathy, is how does this inform what we define as health literacy in the future for Medicare patients. I

think that's really what has to happen. It means that Medicare might become much more vocal about using these kinds of data in terms of value of services, and even in terms of potentially payment for these services. But, this is another area where I think MedPAC can make an enormous contribution. I mean, this is really exciting stuff that you put together. I hope we do a lot more of this.

DR. NAYLOR: So, I just wanted to respond to your recommended next steps. I think that to the extent that we can unbundle low value to be little value, no value, harmful, and to the extent that we can define for whom and bring more clarity to this, I think that would be really, really of great value.

On the issue of altering coverage and payment rules, I noticed that in your terrific report there has been a reduction since 2009, and given all the design differences, five percent versus 100 percent and modifications, so, we're seeing, witnessing reductions in low value -- your analysis did, in 2012 relative to 2009. And, so, one of the things I think would be important to track is the extent to which all of the work on the Preventive Task Force and campaigns, Choosing Wisely and

other, are really accomplishing what might be a positive change in the use of these services without going into the issue of -- especially given the challenges you've outlined in getting low-value services from claims data without getting to changes in coverage.

And, I also think beneficiary cost sharing -- I would be concerned about moving there. I think there is a hunger for information about what is a valuable service for lots of reasons, especially because people are paying out of pocket. But, before we would get to asking them to pay more for low value, I think they need to know that this is a low-value service.

MR. WINTER: If I could just make one point about the comparison between their results and ours, as you noted, our results were lower, but there were several methodological differences between the analyses, in addition to the fact that they did change some of the measures after the publication -- after their publication -- that we used in our analysis. So, I'd want to look at another year of data or two using the same method, and also talk to them about concerns they might have about how noisy some of the measures are.

So, I think longitudinal analysis is really interesting. Potential step to go next. But, I just want to think about that some more and I just want to caution you about using the same -- about drawing conclusions about the comparison of their results to ours. But, it could be there were declines. And, in fact, vertebroplasty, which was one of the surgical procedures, they do agree that there's been a decline in use over the last three years.

DR. NAYLOR: Just in sum, I share the enthusiasm of all the Commissioners about continuing this work. I'm wondering what signals we might have and where we might be able to rely on others rather than changing claims coverage services.

DR. CROSSON: I'll start with standard comment number one. In terms of the, you know, potential avenues to explore to deal with low-value care, and that's delivery system and payment reform, and I think although that doesn't necessarily point directly at additional work, because there's a lot of work that we've done before and work that's ongoing and new ACO models and the like, I think it may have relevance in the sense that we still see difficulty in people actually believing this, and

particularly those who are doing scoring, that down the line, there are avenues for both improvements in quality and cost saving by making some of the changes that are underway right now. I think we saw that and we discussed it earlier today with respect to the SGR reform.

So, to the extent that we could, by broadening the number of low-value care and low-value services that we look at, maybe some larger subset of the 300, and then calculating not just the direct cost of that, but as we mentioned earlier, the downstream costs of that, both from the perspective of adverse impact on patients as well as financial costs, it might help build up the evidence base and the policy base down the line for a better understanding of the value of delivery system and payment reform.

DR. SAMITT: This chapter was fantastic, almost as exciting for me as risk sharing in Part D.

[Laughter.]

DR. SAMITT: I'm kidding. So what I would say is I think --

DR. CROSSON: Are you picking on Cori?

DR. SAMITT: I think it's about time that we

actually have this discussion. You know, I think for me it's the beginning of the retirement of the flawed paradigm that more services leads to better health. And so let's please move forward with more analysis. This is critical.

The one thing, though, that I kept thinking about was how do you sell this, because even though I think beneficiaries are recognizing the importance of this, I think there also is still an expectation around the receipt of certain services, and so I began to think about how do you explain this, how do you articulate it? And what immediately came to mind is I'm not sure we should think about this in isolation. You know, from my point of view, they're two sides to the same coin. While there are a whole bucket of services that we provide that are of low value or no value, I think there are also an equal number of services that we should be providing that we don't, that we don't consistently provide services that are grossly underutilized that if they were utilized would improve quality and improve outcomes. And in many respects, the notion of identifying these services is really a reallocation of resources from things that are not improving health to those that should be reallocated to

improve health.

So I don't know if there's a way to tie this notion of overutilization with underutilization, because in many respects the two parts of that conversation need to go hand in hand.

DR. CHRISTIANSON: I think what I was thinking about saying is a little bit repeating what Bill and Craig said, so I'll keep it short.

I think if we're going to depend on beneficiaries to be one of the mechanisms by which this will all work, we need to really keep focusing on and keep a spotlight on the negative effects on beneficiaries. I don't think there's going to be many beneficiaries who are going to say, "I don't want this service because it's going to cost Medicare more money."

So I think it's important to see, you know, what these services do cost Medicare. But I think it's just as important to highlight what the potential adverse effects are going to be on beneficiaries if they consume, because I think that's what's going to be salient to beneficiaries. So if that's one of the mechanisms that is going to promote change in this area, we need to make sure that stays front

and center as we go forward.

MR. HACKBARTH: Any further questions or comments?

DR. NAYLOR: I just had one idea, which was raised by others, but if there's a way -- I know you can't do it with many of these, but if you were to take one or two, such as PSA screening or something, and see if you could almost in a qualitative way track what happens to people, I think that could be really powerful. Obviously you can't do it for many, but one or two cases of the consequences of the unnecessary test on the long -- it would be -- or if research tells us -- and there are studies that have done that, you know, just a lit review of one or two of them, I think it would be really powerful.

MR. HACKBARTH: Just a thought on the issue of beneficiary cost sharing as a mechanism. I have no doubt that that would be unpopular, and because it would be unpopular, probably very politically difficult to do. And so I get all that. And I also agree that for many beneficiaries, this would be a tough choice that we're framing for them, and there could be inequities by income; you know, higher-income people can afford to pay the higher

cost sharing, lots of issues like that.

But the argument on the other side is that I have a real problem using the taxpayer dollars to pay for services that are proven to be of low value. And it's not just because of the first-order effect on the taxpayers; it also means that there are fewer public resources available to provide some of those high-value services that Craig was alluding to, fewer resources to provide appropriate subsidies to low-income people under the Affordable Care Act.

And so I think that there's a real ethical argument on the other side that we shouldn't be paying a lot of money, Medicare dollars, for low-value services, even though I recognize the inherent political and other difficulties involved in that.

DR. COOMBS: One last thing. One of the things I was thinking about as we were talking around the table is if there was a way to get the low-hanging fruit of the 26, or you could categorize these ones as overwhelmingly low value and there's really uniform consensus -- not that there's not uniform consensus with the others, but target an area that there's absolutely clarity on going forward,

and there was a corresponding communication that is as strong as well. And I think that would help in kind of phasing in this whole new chapter in our goals of looking at low-value and saying that this is going to be an ongoing report card from year to year that, you know -- that literature is changing and results research is being done, and going forward I think it makes it stronger that people look at it as this is a cost in transition. And for medicine, it's not a hard science, and that's what the problem is. I think if it was a hard science, it would be easy to do. But because it's not really a hard science, it makes things hard. But I think it's not impossible to deal with it just as it's actually happening, new literature is coming out, new research is there, and to see it as we're being transformed to better information as we go on, and I think that's very helpful. It's helpful not just for beneficiaries but providers as well.

MR. HACKBARTH: Okay. Thank you. Great work.

We'll now move on to our concluding session for today on using episode bundles to improve the efficiency of care.

[Pause.]

DR. STENSLAND: All right. Good afternoon. Today we're going to talk about incentives to reduce spending during episodes of care, which is not unrelated to the discussion we just had. The goal is to encourage better quality while reducing unnecessary care within an episode.

As we have discussed in the past, the fee-for-service system lacks incentives to improve quality and to eliminate unnecessary services.

In an effort to improve value within the fee-for-service system, CMS developed the value-based purchasing program which ties a small share of each hospital's payments to how well they do on quality metrics and episode spending metrics.

First, we'll review how the VBP program works, and then we'll discuss whether the magnitude of the VBP incentives are at the right level to encourage improvements in value.

The program started in 2013 and by law is scheduled to slowly increase the share of hospital payments that are tied to value-based purchasing metrics.

The hospitals' performance in 2015 on certain

performance metrics will be evaluated and then will affect their 2017 payments under the VBP program. In 2017 and in future years, 2 percent of hospital inpatient operating payments were at risk and tied to value. This essentially acts like a 2 percent withhold. Hospitals that have high VBP scores will receive more than 2 percent back, and those with low scores will receive less than 2 percent back.

Recall that value refers to both quality and spending metrics. The current weighting of the VBP program has a 25 percent weight placed on Medicare spending per beneficiary and a 75 percent weight placed on quality metrics. The quality metrics include the AHRQ patient safety composite measure, three process measures such pneumonia vaccinations, some outcome measures which are currently mortality rates, and patient experience measures.

Today we are focusing on the incentive within the VBP program to reduce episode spending.

The MSPB measure examines all spending that takes place starting three days before admission and ends 30 days after discharges. The spending is standardized to adjust for differences in payment rates across regions. Therefore, it is essentially a risk-adjusted measure of

service use within a 30-day episode. For each discharge CMS computes an actual and expected spending. Hospitals are then informed on the 30-day episode spending for each category of discharge. For example, the hospital would then know if their respiratory cases or their orthopedic cases had high spending relative to the expected level.

As we explained in more detail in your mailing material, hospitals with below expected levels of spending per discharge will see an increase in their payment rates, and those with above expected spending will see a decrease, if quality is equal. A top-performing hospital will expect to receive roughly 0.5 percent higher payments due to the MSPB program and a poor-performing hospital will be expected to receive roughly 0.5 percent less than they would have without the MSPB program.

We examined the variation in episode spending use. In this chart, we standardize spending so the expected level of spending given a hospital's case mix is 1. So numbers less than 1 in this chart refer to hospitals where the average spending is below expected levels given their case mix; numbers above 1 refer to hospitals where the spending is above the expected level. We find that at

the 10th percentile hospitals have spending that's about 7 percent less per episode than expected, and hospitals at the 90th percentile had episode spending that was roughly 9 percent higher than expected.

This tells us that there is about a 16 percent difference in service use between the 10th and the 90th percentiles, and this is equivalent to roughly $3,000 per inpatient episode.

One question that arose in the readmissions reduction program is whether hospitals that serve poor patients will have a harder time achieving low readmission rates, and in that case we said that was true and there should be an adjustment. There may also be a similar question as to whether episode spending tends to be higher for hospitals with high shares of poor patients.

We find that socioeconomic status, as measured by income, does not appear to be a material issue in the Medicare Spending Per Beneficiary measure. In this slide we show a scatter plot examining how the Medicare beneficiary income, as measured by the share of the hospitals' patients on SSI, is related to episode costs. We see a small positive correlation of 0.13. Many high-

episode-cost hospitals that we saw, though, were in the South where post-acute care was high. And a question is whether the higher use in the South is due to having a higher share of poor beneficiaries or was it due to certain practice patterns in some of those communities.

To test this, we examined the correlation between SSI and episode spending in just Northern states -- in essence, a split sample. Let's look at the South, and then let's look separately at the North. If patient income is what's driving the differences across hospitals, then we would expect to see that same relationship in both the Northern and Southern states. We found that in the Northern states the relationship between SSI levels and the MSPB measure was statistically insignificant, and the sign of the coefficient actually flipped to represent a negative correlation.

So given that the magnitude of the correlation is small very small and that the sign of the correlation can flip depending on what part of the country is being examined, we can conclude that patient income is not driving the differences in episode costs. We also looked at this using DSH shares and found a similar result.

So the bottom line is that socioeconomic status does not appear to have a material effect on the differential in spending per episode across hospitals.

Now Carol is going to talk about what does appear to be driving the differences.

DR. CARTER: This slide compares the components of episode spending (that's the pie chart on the left) to the source of the variation in episode spending (which is on the right). On the left, I know the numbers are small, but the two to focus on are: the hospital stay accounts for 45 percent of the episode spending and post-acute care makes up 26 percent. On the right, we display the variation by comparing hospitals with the highest (those are in green) and the lowest (those are in yellow) average episode spending, and those are the top and bottom quartiles (after controlling for wages and add-on payments.)

In the first pair of bars, SNF spending averaged $3,400 for the top quartile hospitals and $2,400 for bottom quartile hospitals, or about 40 percent higher. The differences between top and bottom quartile hospitals were over threefold for IRF spending and over sixfold for LTCH

spending. The differences in home health spending were about 40 percent higher for the top quarter hospitals.

Combined, the four PAC settings make up three-quarters of the difference between hospitals with high and low episode spending. The variation in spending on readmissions (that's the last pair of bars) is smaller than the variation in any single post-acute service. We don't show the variation in inpatient hospital spending because with DRG pricing, there is little variation. Controlling PAC use will, therefore, be key to increasing the efficiency of hospital episode spending.

The MSPB is a simple way to effectively achieve the goals of bundled payment, and it has the advantage that hospitals are familiar with it and are currently operating under it. Some of you may remember our Commissioner Peter Butler once commented about bundled payments: We already have a mechanism, and it accomplishes the same goals and the hospitals are used to it. It's the MSPB. Yet, as Jeff mentioned, the structure of the VBP program creates a pretty small incentive for hospitals to lower their episode spending.

We've identified three ways to strengthen the

incentive to lower episode spending: we could amplify the current MSPB; we could develop an MSPB measure for post-acute-care providers; and we could increase the clarity for hospitals to guide beneficiaries to high-value PAC providers. These options are not mutually exclusive. Some combination could be considered, and we're going to discuss each one in turn.

The most basic way to strengthen the incentive to lower episode -- I mean to increase episode efficiency is to amplify the current MSPB. CMS has the authority to change this, and it could be done quickly. Because the MSPB is a 30-day spending measure, it's a direct way to infuse the incentives of bundling into fee-for-service Medicare.

The impact of the MSPB measure is determined by the amount that's withheld and its weight in calculating each hospital's score.

Therefore, to increase the pressure on hospitals, we could either increase the amount that's withheld from the 2 percent in 2017 to 3 or 4 percent. In addition, the weight of the MSPB measure within the value-based purchasing could also be increased from the 25 percent

share to up to 50 percent.

Another way to increase the pressure to increase episode efficiency would be to put hospital PAC providers at financial risk for episode spending in the same way that hospitals are at risk for episode spending. A PAC measure would begin with an admission to the PAC setting and continue for 30 days after discharge, just like the hospital measure. CMS could implement value-based purchasing for all PAC providers and include a PAC MSPB measure as a performance measure. A PAC MSPB would more closely align hospital and PAC providers since post-acute-care providers would be at financial risk for their own episode spending. SNFs, for example, would have an incentive to shorten their stays, and all PAC providers would have an incentive to more carefully refer beneficiaries to a second and subsequent post-acute-care use.

Just as hospitals get feedback on their episode spending, PAC providers could get comparative information on their episode spending, including information by condition. The IMPACT Act requires the Secretary to specify and for PAC providers to report on resource use

measures, including total estimated Medicare spending per beneficiary. And a PAC MSPB measure could be one of those measures.

Another way to lower episode spending would be to provide hospitals with more clarity on how they can guide beneficiaries to high-value PAC providers. Although hospitals are at risk for post-acute care, they have few tools to guide beneficiary decisionmaking regarding placement in a post-acute-care setting. Typically, discharge planners work with their physicians and provide information to beneficiaries about their PAC options, and beneficiaries have the final say.

In our conversations with private sector entities last fall about how they manage post-acute care, we learned that some establish partnerships between hospitals and high-value PAC providers. In shaping a preferred network of providers, they evaluated potential partners in terms of their geographic coverage, quality, and cost. Fee-for-service beneficiaries were not required to use a preferred partner, but the advantages of using one were explained: receiving more coordinated care, tighter integration of medical staffs, and higher quality of care. We could

explore how such "soft steering" could work in fee-for-service that would retain freedom of choice and strong physician input while, at the same time, ensuring that the networks are adequate and include high-value providers.

As we think about strengthening the incentives of the MSPB, it is helpful to think about how its incentives are aligned with those of ACOs, the other policy that's attempting to control spending. Both policies encourage providers to minimize unnecessary services within the episode, including unnecessary PAC use, physician consults, and readmissions. The policies are mutually reinforcing.

The big difference between the two is that the ACO policy includes an additional incentive to control the volume of episodes. This is because ACOs are at risk for a population. In contrast, the MSPB does not discourage the volume of episodes. In fact, hospitals may have a small incentive to admit the marginal, most likely lower-complexity case as a way to lower their average spending per episode.

Scott and other Commissioners have commented that we spend a lot of time focused on how much Medicare spends for units of service and less time on how to control units

of service. In addition to the existing ACO program, one way to discourage episodes is to develop an admission policy. The idea here would be to penalize providers with high rates of potentially avoidable hospital admissions, similar to the readmission policies for hospitals and soon for SNFs.

An admission policy requires calculating a rate of expected admissions for a given population. Rates for nursing homes would be relatively straightforward to develop because we could use their long-term-care residents as the population. Some of the avoidable admissions from nursing homes are beneficiaries who are admitted to hospitals to recertify them for their Part A coverage, the churning that we've talked about before.

Hospital rates would be trickier to develop and administer. We would have to define the geographic area and then calculate a rate, and that's the easy part. The harder policy questions are, first, how to hold multiple providers in an area jointly responsible for the rate and, second, which providers to hold accountable. We know that policies that involve joint responsibility are not very effective at changing the behavior of individual actors.

In terms of which providers, patiently avoidable admission rates reflect the adequacy of the ambulatory care system and hospitals' inclinations to admit the marginal patient.

Past Commission discussions have indicated a reluctance to hold fee-for-service providers jointly responsible when the entities have little relationship to each other. Another complication is that changes in volume could reflect beneficiaries seeking care at better quality providers, which the program would want to encourage. So while a hospital admission policy might be possible, these issues would need to be worked through.

This concludes our presentation. We'd like to hear your thoughts on how to increase the pressure under fee-for-service to lower episode spending. Options identified include amplifying the current MSPB, developing an MSPB for post-acute-care providers, guiding beneficiaries to high-value PAC providers, and ways to discourage the volume of episodes.

MR. HACKBARTH: Okay. Thank you.

Clarifying questions, please.

DR. NAYLOR: So I'm wondering if you could clarify how the PAC MSPB is different from the bundled

payment model 3?

DR. CARTER: It's pretty similar in that they both start with the beginning of a post-acute-care use, and they follow a beneficiary through either 30 or 60 or 90 days. So in that sense, the risk and sort of the services that are include are similar.

The big difference is that the bundling initiative is voluntary. Those that are opting in are putting, I think, relatively few numbers of conditions at risk. And, finally, the time frame of that is pretty long in the sense that the bundled initiative, providers have to decide to be at risk by July, and then finalize the conditions that they're going to be at risk for by October. And then there's a three-year evaluation -- performance period and then an evaluation.

So in broad gauge, they're similar. What we were thinking is that the MSPB we could sort of do pretty soon. And so in that sense, I think they're on different time frames for actually implementing something relatively soon.

MR. GRADISON: In our earlier work on payment updates for three of the silos, including hospitals, we came up with a definition of efficiency, which was based

upon, of course, cost and quality. The question is: Specifically with regard to hospitals, are we using the same measure here that we used in doing the chapter on -- which was in our March report, on hospitals?

DR. STENSLAND: In the March report on hospitals, we're using just the hospitals' costs. But we could shift to using episode costs or a combination of the two.

MR. GRADISON: I just was wondering about the consistency of the -- trying to see whether we might, if we haven't already done so, move to a consistent measure. And perhaps we've already done that. That's all.

DR. STENSLAND: Yeah, the questions are a little bit different, and the hospital one is: Is the hospital able to deliver their services for a lower cost? And we're really looking at the hospitals' costs. In this measure, it's really looking from the Medicare spending, so it's really looking from the Treasury's perspective. Can we get this done without the Treasury putting a lot of money out the door, which is different than the provider's cost? But I think you have a good point.

MR. GRADISON: Thank you.

DR. NERENZ: Slide 11, please. The first bullet

point where it says hospitals are at risk, is this referring to anything other than the current MSPB and the readmission?

DR. CARTER: No.

DR. NERENZ: Okay, good. So the actual amount at risk is really small here, right? Fractions of a percent?

DR. CARTER: [Nodding head.]

DR. NERENZ: Okay.

MS. BUTO: So just two quick questions. One is about the increase we're seeing in hospital admission rates. So if we're looking at one possible factor of identifying what measures or what appropriate admissions rates might be and how to set a threshold for that, you know, what do we know about what the rate of growth is in admissions? Are we seeing that to be a real problem?

And then, secondly, isn't there a difference between the MSPB versus bundling in that bundling would be sort of an ongoing prospective payment versus MSPB is more of a reconciliation after the fact? I'm just curious. Do we think the payments would flow in the same way? And the reason I ask is my sense of bundling is if, in fact, it is given prospectively, there's more of an opportunity to be

for active management versus waiting until, you know, the episode has long passed, and then looking to see what happened, and then sort of trying to take that on board.

DR. CARTER: So most of the bundling initiatives actually are not, prospectively. The money flows fee-for-service, and then there's reconciliation done at the end.

MS. BUTO: So they are basically identical in the flow of money is what you're saying?

DR. CARTER: Yes.

MS. BUTO: Admission rates. Are they growing fast?

DR. STENSLAND: No. The admission rates generally have been declining. So the question is not the trend, but the question is, Is the level as low as we would like? We still think that there is maybe some excess readmissions, and one of the concerns is while the admission rates are generally declining across the country, there still is a fair amount of regional variation with some places having a lot higher readmission rates than others, and there is a question is all those other admissions necessary in those regions.

DR. MILLER: The only other thing I would add,

Kathy, is, I think, if I followed your comment about how is it different than bundling, there may be some view down the road in the bundling demonstration that you actually get to and up-front payment that then the person manages -- or whoever the actor is manages over time.

And another way to think about this is, well, at least you can inject some feeling into how much you amplify it in the existing measures, of managing on that basis before the real thing comes along, if you want to think about it that way.

I think that's what we kept hearing from hospitals. Hospitals were saying, "I'm already starting to think about this. Why when everybody talks about all this bundling stuff does nobody come back to this thing that actually arrives in my office once a month and sort of tells me what's going on over a 30-day period.

MS. BUTO: And I was just reacting to this notion of you find out later whether or not, you know, versus potentially if you -- more like capitation or some kind of up-front payment where you're trying to make tradeoffs, that's happening at the time the money is flowing, but that may just be a distinction without a difference.

MR. HACKBARTH: Clarifying questions, anybody?

[No response.]

MR. HACKBARTH: Okay. Round 2. Craig.

DR. SAMITT: So focusing on the discussion topics, I am glad you said that these aren't mutually exclusive because, as I began to think about which one would be most effective, I recognize that at least the first three, in my mind, they're at least equally effective, and in fact, the way that I am thinking about it, is amplifying the current MSPB highlights why this should matter -- the hospital developing a PAC MSPB underscores why this should matter to the PAC. And the third, in terms of guiding beneficiaries, is an avenue by which to engage and persuade the beneficiary to utilize the high-value services, so I think one without the other two is somewhat less effective. So I would advocate for all three.

I guess we could process the pros and cons of each individually, but I think that together, it's the most powerful solution.

The one that I am not comfortable with is the last. I mean, as I heard you discuss sort of how does one

go about achieving joint accountability for reducing inappropriate hospitalizations, it made me think, well, isn't that what we are trying to accomplish with the ACOs, and should we -- with either the next-generation ACOs or the existing ACO models give that program an opportunity to work, to see if it works, before developing yet another option to achieve community-wide joint accountability for population health.

MR. HACKBARTH: Just say a little bit about the relationship between this and the readmissions penalty. It seems to me readmissions are a subset of what this potentially gets at.

DR. STENSLAND: I have a little slide here that helps a little bit.

The readmission penalty is what you see on the right, and that is really the bottom part of this slide. Hospitals that have high readmission rates, their inpatient payment rates decline slightly up to a 3 percent maximum reduction for those conditions that are covered by the readmission penalty.

Now, for the 30-day episode, that generally increases your rates, meaning you get some money back from

your withhold as you have lower and lower 30-day episode costs, and part of that 30-day episode cost is the readmissions, but the readmissions is really a small part of it. It doesn't really move the needle too much.

So the incentive to reduce your readmissions is really driven by the readmission penalty, and the amount of the incentive that flows through the MSPB program is really small. It adds a little bit of extra incentive on top of what we are getting through the readmission penalty, but not a whole lot.

MR. HACKBARTH: Let me just be the devil's advocate for a second. If readmissions are such a small portion of the added cost, maybe that means there's too much weight put on readmission penalty here, and it ought to be just subsumed under a total measure of 30-day post-discharge performance.

DR. STENSLAND: I think if I was going to be the counter to the devil's advocate, I would say one thing you could argue is that the readmissions are something different from a lot of this extra spending. Like the extra spending might include an extra consult while you're in the hospital or an extra home health visit, and you

could say those things are not particularly bad. They might be wasteful, but they're not particularly bad.

On the other hand, a readmission represents a really bad outcome for the patient, and we merely might want some stronger incentives to reduce those readmissions, and it looks like so far it's working. That would be one thing. It's a different animal. It may be something we really want to put some more emphasis on.

The other thing is that the readmissions are -- the variance of the readmissions is not super huge between hospital to hospital, and it's that variance that looks at the variance in the MSPB 30-day measure.

MR. HACKBARTH: Okay.

DR. SAMITT: Correct me if I'm wrong, but isn't it conceivable that these work in opposition? If you are seeking to avoid a readmission penalty, you may very well drive up the post-admission cost because you're more than likely going to want to use a post-acute care facility to assure a non-readmission to the hospital, and so I would imagine that they definitely work in opposing directions.

MR. HACKBARTH: Is that a good design or a bad design or indifferent?

DR. SAMITT: Well, I think we'd want to compare and contrast the total costs in each scenario. So while you would want to avoid readmission, in some respects, neither is good. You wouldn't either want frequent readmissions nor would you want an excessive use of post-acute. So what is the combination of those incentives to really get to the optimal admission and post-admission outcome?

MR. HACKBARTH: I'll let you go in just a second, but I do worry about a proliferation of bonuses and penalties for readmissions and HACs and now this, and I really think that if another one is going to be added, it really needs to be thought of strategically. How does this fit with the others? Are they mutually reinforcing? Are they conflicting? What are the right proportions? Should they be penalties and bonuses in all cases as opposed to just throwing one more thing in an already-complicated mix of payment incentives?

Other -- Herb.

MR. KUHN: So I would agree with that comment. I think these payment systems do need to work seamlessly and they don't appear to be layering one another as part of

that.

I am glad you mentioned the HAC, the hospital-acquired condition, because if you look going into 2015, you've got now with the three of them -- that is, the readmissions or the rehospitalizations, the value-based purchasing, and the HACs -- you've got 5.5 percent, and that is going to grow next year to 5.75, and the year after that in 2017, it will be up to 6 percent. So it's continuing on a scale moving forward.

All these things that we have up here, I think they're worth continuing to explore and to look at, with the caveat, as we talked about, how they can seamlessly work together.

The one thing that would be helpful for me, though, as we continue to review on this is what the literature shows or how much of either an incentive or penalty really motivates the changes in provider type that's out there.

So, on the hospital side, there are some who have made the arguments, at least I've heard and read, that maybe 2 percent, 3 percent is enough to change that behavior because that translates into around $100 to $150,

I think, per discharge, and that's enough to get people's attention and change behavior.

On the physician side, I've heard people say that it's got to be something north of 5 percent, maybe even as high as 10 percent -- even more than that. So it would be nice if we could in the future understand what does the literature show in that and what's kind of the range that we're talking about as we move there.

And the final thing I would just say is that as we look at the Medicare spending per beneficiary component, that really only is beginning this year, and I don't want this to be an impediment for our work going forward, but historically, in the Medicare program, you've let programs kind of start, get a chance to look how they're working, evaluate, and then you start the refinement process. To start a refinement process, the year one, and begin tinkering with it, I don't know whether that's a good thing or bad thing, but it goes against historic norms. I just think we need to take that into consideration and understand. Do you start tinkering with something before it's even really begun?

MR. HACKBARTH: Round 1. Any more Round 1

clarifying questions?

[No response.]

MR. HACKBARTH: Round 2. Go ahead, Cori, and then Jay.

MS. UCCELLO: So I'm attracted to this idea of the soft steering and that kind of thing, but I'm wondering, just stepping back, how much freedom or choice or control do beneficiaries actually have now in terms of post-acute care use. How much are they already relying on the hospitals to steer them to where they should be going?

DR. CARTER: We did talk with private sector, both systems and ACOs, so they're running in fee-for-service, and so benes have freedom of choice. We heard things like they had a preferred network, but they had a lot of leakage, and so even though they were recommending -- and so that was doing better than not recommending, they had leakage of like 50 percent. Those were just the handful of people we talked to. Obviously, in the MA world, it's totally different.

I think what I'm hearing in your question is it's true there's a lot of guiding going on now, but there also is a lot of leakage and for good reasons. Patients want to

be close to their families, and so they may opt to not go to a recommended facility or for whatever reason. But I think even with current guidance going on, benes are still making choices that may not align with where they are being recommended to go.

DR. HOADLEY: I'm intrigued by both of these last two lines of conversation. It does seem like it's hard to figure out what beneficiaries are using information, and you've obviously got some insight, which you just offered, and then what different kinds of tools could do to do it. But let me go back to Herb's comment, because I've had the same thought about these financial incentives. I know at one point, doing some interviews with physicians and asking them about -- I have no idea at this point what the particular example was, but about the effect of some kind of bonus system, and you often got the answer, "Well, I don't even know what's coming in. It's sort of lost in the midst of lots of payments that come in."

On the other hand, we hear a lot about the impact of the Star ratings bonus in MA, that it does seem to become quite a focus, and you see lots of -- again, it's anecdotal, but a lot of trade news stories that suggest --

and I think folks here have talked about it too -- that once you've got these things, they're going to really pay attention, how can we up our score on this particular thing, because there's some money at the other end and maybe less of that in Part D plans because there's no money at the other end, although even there, even before the money was attached to MA, there was that sense of some value and sort of having certain Star levels and just for the public view of it.

But it does seem like if there's some ways to better understand how these different kinds of bonuses and withholds and things translate, how they're perceive, how they're received, in other words, what form do they come, do they come with labels, do they come in advance, to Kathy's point, where you can say, "Okay. Here's money. It's contingent on these things," versus it's a little fuzzier in terms of you're getting something and somebody is going to reconcile later. It seems like if we could understand that and how that differs across sector and across some of these different programs, that might help us get a better sense of how to set these things up going forward.

MR. HACKBARTH: One of the things that I like in the pending SGR bill is that at least they made some effort to take what had been totally sort of unrelated bonuses and penalties and put them into a more integrated system with an overall score and a single payment or a penalty, up or down, and I think maybe some of the same sort of work could be useful in the hospital world as well as opposed to just piling new things on top, as has been the practice to this point.

Warner.

MR. THOMAS: I would agree with your comment, Glenn, and I think there is a lot of kind of disparate measurements, incentives, penalties. I guess, as I read through this, certainly, there's things that can be improved. I was just trying to get to what are we trying to accomplish. Are we making recommendations to the whole bundled program? Are we talking about how this fits in with other programs? I was trying to figure out where we were going with the discussion.

DR. MILLER: I think there's a couple of different ways to talk about this here.

I don't think there is any inherent resistance to

the notion of looking across a set of incentives and saying how could we rationalize across them, and if that's the direction you wanted to go on this, we could certainly -- and would certainly be willing to do that.

I think the motivation here -- and I swear to God, this is true. A lot of this came out of talking to hospital people who said there's a lot of other things out in the area, and I would just add to Jack's list, there are certain things that get people's attention. The Stars clearly have people's attention. The readmission penalty clearly has people's attention. There's also some other noise out there that people are less clear, and what was kind of striking to us is we would go to these rooms to talk to different hospital people and that kind of thing. This incredibly geeked-out measure, they were all aware of, and actually, many of them were using it and then sort of asking -- to questions that occurred over on this side of the conversation, there is all this churning unbundling, and it doesn't sound like it's going to happen anytime soon, and I'm not sure how to even get involved in it. Why aren't policy people talking about this? This creates the same kinds of incentives.

And then the third thought that I linked it to is something you brought up in our conversations a few times back, which is why don't you give me more tools to manage what happens outside my hospital? And I'm sure I'm not doing your comments justice, but that type of thought, and so we started looking at this and thinking about whether this gave a platform to pull many of those thoughts together. No resistance to the thought that, look, if we have too many bells and whistles, put them in one place, or get rid of them someplace, and put something else in place, no resistance to that.

But those were the thought processes that kind of brought us to this.

MR. THOMAS: I think that's helpful because I would agree that the -- I mean, people talk about bundles, but as far as the traction it has compared to readmissions or compared to the Stars program and MA, it's a much lower priority. It's not getting the same sort of traction. So I think the idea is to try to get more traction there, to try to make it more attractive and contain a modifier, that could be interesting for some hospitals that are not going down the road of more of a global payment of the ACO model.

MS. BUTO: On this same point, to me the difference is who you think actually has control. So, if suddenly, Medicare says to hospitals, we're giving you the bundle for post-acute care, up to 30 days, that's a whole different game than saying we are going to tweak your MSBP and hope that you have more drive to influence that decision, or even second bullet, which is PACs, whoever your governance is, you're going to get a certain reward, depending on how that's managed.

So, to me, it's sort of back to who controls this, and then the mechanism for getting the money to them is maybe less important, and maybe you try to do it in the least disruptive way possible. But if we had a better sense of who we think is in control, I think that helps a lot in figuring out how powerful any of these things actually are.

MR. HACKBARTH: I agree with that, Kathy, and to me, in an ideal world, the financial responsibility is aligned with the control, as you put it. And, to say, oh, we are going to penalize you for something that happens outside your four walls, hold you accountable for something that happens outside your four walls, is -- that's been a

point of controversy around the readmissions penalty from the beginning.

And, one way that we dealt with that and the world has dealt with that is to say, well, it's a relatively small penalty and what we're trying to do is nudge hospitals towards accepting more responsibility for what happens outside their walls. But, because the dollars don't match up with the accountability, there's only a limited amount of penalty that you can apply, and that means the limited amount of effect that you're likely to have.

If you want a much bigger effect on what happens post-hospital admission, I think you need to go to a true bundle and say to the hospitals, you're accountable, but you also control the dollars. And, so long as the accountability and control over the money is separate, there's going to be a limit on what you can expect of them.

DR. MILLER: And, I just want to add, I agree with all that. And, the other point that you touched on, and I would just draw it out a little bit further, there's this ongoing dilemma, and you hear it here all the time, which is why can't we move people to taking truly more

risk, you know, move people to an ACO, just to use it as an example. And, as long as fee-for-service -- and, I'm not saying make it unnecessarily and just arbitrarily complicated.

But, as long as fee-for-service is a fairly comfortable place to be, people aren't going to move, and you can sort of think of these changes, too, because even in your exchange where you say, you know, what really matters here is giving them the money tomorrow and giving them the responsibility. We also know the monumental resistance to that idea, both on where the fact that certain actors would lose control of their money and certain actors are not ready to take control of that money. This kind of thing can represent a bit of a bridging step if it is done in a rational way where a few things are put together.

MS. BUTO: Yeah, and I'm not disagreeing with that, Mark. I just don't want to lose sight of the fact that life would be simpler, and we would get to where we want to go -- so, let's not lose sight of the bigger kind of impact that a big change could have, albeit we're not ready to go there yet, but --

DR. MILLER: [Off microphone.] I hear you.

DR. NERENZ: I was going to make a similar comment to the one Kathy made, so I'll try not to just duplicate it, but I was struck in reading the materials about how hospital-centric this whole presentation was, starting with the selection of the episodes, that they are defined by an admission, even though there are many other clinical episodes that are not necessarily so. But, I understand that you've just taken this as a frame for discussion.

But, as I went through the chapter, in reading it, I was looking for the point where we'd say, well, how about having physicians accountable or physicians somehow in this picture somewhere, or even a little more precisely, how about patients who are formally aligned with Certified Medical Homes. How about having the medical home -- and it was never in there.

So, I think the line of this discussion -- again, I'll just call very hospital-centric -- and I'd echo Kathy's question. Is that really now the way the scope of responsibility and authority really runs? Do hospitals really control this whole set of things that drive costs,

including the fee schedule element? Meaning, do hospitals control payments to doctors? That seems a little odd.

And then looking forward, is that how we want the world to be? In this set of episodes, do we want hospitals running the show? Now, maybe we do, but there may be other alternatives.

DR. NAYLOR: So, I just want to echo those points. I walked away reading this chapter with the same kind of sense of what is the goal? Is the goal to get to a more efficient spending for a given episode, or is it -- I actually like point four, trying to figure out ways to discourage unnecessary acute care episodes that result in unnecessary hospitalizations and so on.

I mean, much of our conversation has been to think about how it is that -- where our energy should be in terms of enabling community-based providers to guide the care of Medicare beneficiaries, and I think that this is where we should be placing our attention going forward.

MR. HACKBARTH: Other questions, comments?

[No response.]

MR. HACKBARTH: Hearing none, I think we're done. Thank you all.

Okay. We will now have our public comment period.

DR. MILLER: Carol, can you put up the public comment slide? Thanks.

MR. HACKBARTH: Seeing nobody go to the microphone, we are adjourned.

[Pause.]

MR. HACKBARTH: It's over, George.

[Laughter.]

MR. HACKBARTH: Go ahead, George. You're special, so we'll --

MR. GEORGE MILLER: Thank you. I just stood up to thank Glenn for his great service to MedPAC on behalf of all the Commissioners and the public. This is the first time I've had this opportunity to be on this side of the microphone, and I'll try to keep it under two minutes, but --

[Laughter.]

MR. HACKBARTH: [Off microphone.]

MR. GEORGE MILLER: But, Glenn has been a great Chairman. On behalf of all the Commissioners, I wanted to stand and rise and thank you for your great, great service

and your great leadership over MedPAC over these 12 years.

[Applause.]

[Whereupon, at 3:53 p.m., the proceedings were adjourned, to reconvene at 8:30 a.m. on Friday, April 3, 2015.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
International Trade Center
1300 Pennsylvania Avenue, NW
Washington, D.C. 20004

Friday, April 3, 2015
8:30 a.m.

COMMISSIONERS PRESENT:

GLENN M. HACKBARTH, JD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHY BUTO, MPA
ALICE COOMBS, MD
FRANCIS “JAY” CROSSON, MD
WILLIS D. GRADISON, MBA
WILLIAM J. HALL, MD
JACK HOADLEY, PhD
HERB B. KUHN
MARY NAYLOR, PhD, RN, FAAN
DAVID NERENZ, PhD
RITA REDBERG, MD, MSc, FACC
CRAIG SAMITT, MD, MBA
WARNER THOMAS, MBA
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AGENDA PAGE

P R O C E E D I N G S

[8:30 a.m.]

MR. HACKBARTH: Good morning. Nancy and Katelyn are going to lead this morning with bundling for oncology services.

MS. RAY: Good morning. Medicare's payment policies for Part B drugs do not always provide beneficiaries and taxpayers the best value because the policies do not consider evidence on a drug's comparative clinical effectiveness compared with its alternatives.

Physicians have raised this concern. In one instance, physicians from a cancer hospital announced that a new cancer drug would be excluded from the hospital's formulary because the new drug offered the same survival benefit and a similar side effect profile as its alternative but was twice as expensive.

At the fall Commission meetings, we discussed policies that aim to improve the value of Part B spending for drugs and biologics.

We discussed Medicare's application of least costly alternative policies between 1995 and 2010. For two or more drugs that clinicians prescribe for the same

condition and produce a similar health effect, the policy bases the payment rate on the least costly product.

We also discussed bundled approaches under which Medicare would establish one payment for Part B drugs and other medical services furnished across one or more settings and by one or more providers during a defined period of time for a given condition.

Some have reservations about Medicare's role in developing LCA policies, about Medicare grouping drugs and deciding which drugs result in similar health effects.

In contrast to LCA policies, bundled approaches permit clinicians rather than Medicare to decide on the value of a service covered by the bundle -- for example, drugs. In addition, bundled approaches, depending on their design, might lead to improved care coordination.

Based on Commissioners' request, today Katie and I are going to focus on bundling oncology drugs. We focus on oncology drugs because Medicare spending for oncology drugs -- that is to say, products that treat cancer and its side effects -- accounted for about half of total $11.7 billion in spending for Part B drugs furnished in physicians' offices and paid based on the average sales

price in 2013. To put it in another way, 45 percent of the total $11.7 billion in Part B drug spending was paid to oncologists in 2013.

So first I will present preliminary findings from an exploratory analysis that examined Medicare spending for oncology services. Then I will review key design elements to consider when bundling services. Katie will then present case studies on bundling approaches used by commercial payers and Medicare.

The goal is to include the material we are presenting today and our earlier work on LCA policies in the June 2015 report.

So we analyzed 100 percent claims data so we could begin to learn about the spending patterns of oncology care and to assess the spending that oncologists can affect. To be clear, our goal here was not to create a bundle. Our study population of about 61,000 beneficiaries consists of newly diagnosed beneficiaries with three major cancer types -- lung, breast, and colon -- who were diagnosed in 2011 or 2012 and who received a Part B oncology drug between January 2011 through June 2012.

The mean length of an episode, the mean length of

time we followed a beneficiary on average was 162 days. About 20 percent of the study population died during the 180-day follow-up.

Here are our preliminary findings: 180-day spending for Part A and Part B services averaged nearly $41,000 per beneficiary. This total includes: outpatient oncology drugs and their administration furnished at physician offices and hospital outpatient departments, that is the red slice; other physician/supplier services, that is green; institutional outpatient services, yellow; inpatient hospital services is orange; and home health and hospice is lavender. At the 25th percentile, total spending averaged about $21,000 per beneficiary while at the 75th percentile spending averaged $54,000 per beneficiary during the 180-day follow-up.

From this slide, oncologists directly manage the 46 percent of spending for outpatient oncology drugs and their administration costs. In addition to spending on oncology drugs, there is a block of dollars here that oncologists may also have opportunities to affect -- for example, the 20 percent on inpatient hospital services.

So here we show you our preliminary findings that

look at spending for outpatient services: physician/supplier services and institutional outpatient services. This is a subset of spending from the previous slide. It includes spending for services furnished in physicians' offices and hospital outpatient departments. These two service types account for 76 percent of total spending.

This slide shows 30-day outpatient spending for oncology drugs and their administration, that is the red bar; radiation oncology services, that is green; and all other outpatient services, that is yellow. So I'd like to highlight three points here.

The first point is that spending during the first 30 days is intense, and then it drops between periods 2 through 6.

The second point is the substantial spending for radiation oncology services; that's the green bar. During the 180-day follow-up period, radiation oncology services accounted for 9 percent of total spending. This is another service type that oncologists can influence.

The last point concerns the group "all other outpatient services." This group also includes some

services that oncologists can affect, including imaging and laboratory services, and services associated with furnishing major procedures and other procedures.

Developing bundles that include Part B oncology drugs and biologics might help address the incentive under Medicare's current Part B payment method for providers to furnish more costly regimens when therapeutic equivalent drugs exist. It might also lead to improvements in care coordination. I'm going to summarize six key design elements to consider when bundling services. In our June 2013 report, the Commission examined these elements with respect to bundling PAC services.

The first element is deciding on the services included in the bundle. Bundles that include more services require providers to be accountable for a wide range, thereby creating greater incentives for care coordination than a narrowly defined bundle. Katie will be discussing oncology approaches that range from the narrowest approach covering the cost of oncology drugs and their administration to the broadest approach which would cover all services.

The second element is deciding on the duration of

the bundle. The oncology case studies show approaches that range from one month to one year.

The third element is selecting the trigger event. Some of the case studies start the bundle at cancer diagnosis while others start the bundle at the oncology treatment -- for example, chemotherapy.

The fourth key design element is deciding on the type of payment. Several of the case studies pay providers prospectively while others maintain fee-for-service payments and adjust payments retrospectively.

The fifth key element is adjusting for risk. The case studies use measures on disease severity and cancer type and stage.

And, finally, the sixth element is countering the incentive to stint, which the case studies address by including outcome measures such as patient survival.

Now Katie will take you through several of the case studies we included in your briefing paper.

MS. SMALLEY: So you may recognize this slide from previous meetings. In a 2011 Health Affairs article, Peter Bach and colleagues outlined a bundling proposal for cancer care in Medicare. The bundle would be relatively

narrowly defined. They discussed covering the costs of chemotherapy drugs and their administration during an oncology episode, but mention that more services could be incorporated into the bundle over time. The design of the bundle would be informed by evidence-based guidelines for cancer care, and payments would be periodically readjusted to account for the cost reductions associated with bundling.

The goal of this type of bundle is to incent the use of low-cost, but effective, drug therapies. This would be managed by adherence to standards of care for each condition, which Bach envisions that Medicare would certify. Bach noted that financial structures like risk corridors or shared savings could also be built into the model to strengthen the incentives.

An advantage to this approach is that, because the scope of the bundle is limited, the oncologist is in control of the treatment regimen, and few others would be involved. This situation would make the bundle more straightforward to implement. On the other hand, the narrow scope of the bundle gives the oncologist fewer options to realize efficiencies in the delivery of care.

While they were not detailed in the paper, Bach also acknowledged the importance of addressing issues such as cost shifting, upcoding, and stinting in designing a successful bundle.

In contrast to Bach's proposal of a narrow bundle, UnitedHealthcare and MD Anderson have collaborated on a relatively broad bundle for head and neck cancer. MD Anderson is responsible for the total cost of cancer-related care for that patient, including complications, and is paid with a prospective payment, which they describe as similar to a DRG. Based on historical data for similar cases, United and MD Anderson negotiated a prospective payment amount for eight different bundles, based on the type of cancer therapy being provided.

A multidisciplinary oncology team decides if surgery, radiation, chemo, or some combination is the most appropriate treatment for a particular patient. The diversity of the members of the team encourages a choice of treatment that is consistent with the evidence of the best treatment for the particular patient.

From the patient perspective, there is the added benefit of only one bill to pay. They know the amount that

they are responsible for up front, and there are no surprises as they go along.

Another UnitedHealthcare pilot, which we discussed in detail at previous meetings, specifically targets drug treatment for oncology episodes. The insight is that paying for oncology drugs via ASP plus some add-on provides a revenue incentive to prescribe a particular (more expensive) drug, without much regard to quality. They wanted to remove that incentive and strengthen the incentive to evaluate drugs based on their effectiveness and prescribe on that basis alone.

To do this, they separated the drug add-on from the drug and repurposed it as a fee that could be used to provide services like in-hospital care or hospice management if the patient and oncologist decide to discontinue treatment.

Provided that the survival rate improved over the cycle, the oncologists were also eligible for shared savings. From 2009 to 2012, spending was reduced overall by about $33 million, $11 million of which went back to the practices. Interestingly, however, drug spending during that time increased. It seems that total spending went

down because of decreases in hospitalizations and radiology. It's not clear what drove the large increase in drug spending; however, because this is a larger bundle and the benchmark holds providers accountable for all services, not just chemotherapy, if a more expensive chemo regimen is appropriate, oncologists have the opportunity to prescribe it.

CMMI has also proposed an oncology episode payment. In the oncology care model (OCM), participating practices will agree to practice transformation efforts such as 24/7 access to the EHR, adherence to nationally recognized clinical guidelines, and providing patient navigation and comprehensive care plans, with the intent to improve coordination and quality of care for beneficiaries initiating chemotherapy. CMS plans to initiate the model in spring 2016.

The episode is six months in length, but can be renewed for as long as chemotherapy is administered during the five-year model. Quality monitoring is composed of 39 measures, which fall into domains including care coordination, patient experience, population health, and adherence to practice requirements. A subset of the

measures is used for the purposes of performance-based payment.

On the next slide, we will discuss the payment arrangement in more detail.

The episode maintains most aspects of fee-for-service payment, including paying ASP+6 percent for Part B drugs, but with the addition of a $160 dollar per beneficiary per month payment to support practice transformation and care coordination efforts. The PBPM is paid to the oncologist who first orders chemotherapy and is paid for the duration of the six-month episode, regardless of whether chemotherapy ends before six months or if the beneficiary chooses to go to another provider. The PBPM can be renewed for beneficiaries on chemo for longer than six months, until the end of the demonstration.

Performance in the model is determined every six months by combining the participant's actual expenditures over the period with a benchmark, or target price. The actual expenditures include all fee-for-service A and B spending and some Part D, plus the per beneficiary per month payments. The target price is calculated from historical fee-for-service A, B, and D expenditures --

which are trended forward to the performance year, and then risk adjusted -- minus a 4 percent discount rate. If the practice achieves actual spending below the target price, then they are eligible to share in savings. The amount of savings that they are eligible for depends on performance on a subset of the quality metrics.

While the PBPM may lead to better care management among participating practices, the size of the payment relative to practices' drug administration costs may lead to increased total Medicare spend that is not met with gains in quality or access.

Similarly, the shared savings arrangement may provide an incentive to lower costs, but the lack of a requirement for a two-sided risk arrangement lowers that incentive.

In conclusion, bundled approaches allow clinicians to provide high-value services to their patients. Our exploratory analysis found that, for the three cancer types we looked at, oncology drugs and administration account for a significant portion of spending on oncology over a six-month episode. However, oncologists have the opportunity to make judgments that

affect their patients' treatment regimen, hospitalizations, and other utilization, making this an area amenable to bundling and other episode-based approaches.

We welcome Commissioner feedback on the design of bundled oncology approaches in this session, and we are happy to answer any of your questions.

MR. HACKBARTH: Thank you. This is really interesting.

Could you put up Slide 5 -- or, actually, I guess it's 6, the graph. Or, no, put up 5. That is easier to talk about. Thanks.

So this is the pattern for lung, colon, and breast cancer. Do we know whether the pattern is significantly different for other types of cancer?

MS. RAY: I did not look at the other types of cancer yet. That's something that we can do moving forward.

MR. HACKBARTH: Okay. And then we've used the first administration of an oncology drug as the beginning of the episode. Do we know anything about what the expenditures look like before that?

MS. RAY: That is something I can get back to you

on. I don't have that material here, but that is knowable.

MR. HACKBARTH: Okay. So Round 1 clarifying questions. We'll come down this way, starting with Kathy.

MS. BUTO: So I wondered if you could give us just a thumbnail of the difference between the two UnitedHealthcare demos or pilots. I couldn't figure out exactly what elements were different. And if you could also comment on whether -- I think one of them is a prospective payment. Was the first one also a prospective payment, or was that something else? So both the payment design and also what are the key differences?

MS. SMALLEY: Sure. So the first one that I talked about, this is for a very small subset of cancers. It's just for head and neck cancer. And it's also limited to patients that are being treated for cure, and so they kind of have a different set of services, and MD Anderson worked to create a true bundle around those services, so they get a prospective payment on that.

The other model is kind of broader, and it's not necessarily a bundle in the way that we typically think about it in that there's no prospective payment. It's kind of the change is that the drugs are paid at ASP plus zero,

and then that contracted add-on that used to be attached to the drug payment is paid in an episode fee.

MS. BUTO: Just one follow-up. On the first UnitedHealthcare demo, you've got a team deciding on best course of treatment. So were there different bundles or different -- for surgery, radiation, and chemotherapy?

MS. SMALLEY: There are eight different bundles based on the different mix of services.

MS. BUTO: Okay. So that's -- there wasn't an overall bundle or an overall amount.

MS. SMALLEY: Right.

MS. BUTO: Gotcha.

DR. NERENZ: On Slide 6, please. The first 30-day period obviously is more expensive than the others, and I just want to make sure I'm understanding why that might be. These are, again, people -- only those people who got at least one Part B drug, so we're not seeing an effect of, say, surgery only here, and it's outpatient, it's not inpatient. And the red thing is higher. Is there just an obvious explanation of why that first 30-day period, particularly for drugs, is so high?

MS. RAY: Well, everybody is in that first

period. By definition, you have to be in that first period

DR. NERENZ: So then it gets lower because people fall out of it?

MS. RAY: Well, 20 percent of the study population died in the 180-day period, in the six months.

DR. NERENZ: Okay.

MS. RAY: So clearly -- well, I don't know yet, but if the trigger point was cancer diagnosis instead of the first administration of an oncology drug, that could give a different pattern.

DR. NERENZ: Well, that's just what I want to make sure we understood.

MS. RAY: Right. It could, yes.

DR. NERENZ: But it was not that. The trigger point is the first claim for a Part B drug.

MS. RAY: Yes.

DR. NERENZ: Okay.

MR. HACKBARTH: So, Nancy, could I just make sure I understood that? For this calculation, the denominator for the per beneficiary calculation includes throughout the period all of the beneficiaries who were in the initial denominator --

MS. RAY: Yes.

MR. HACKBARTH: -- even if they've died during the period.

MS. RAY: If you died in Period 2, you're included in Period 2, but you're not included in 3, 4, 5, or 6.

MR. HACKBARTH: Okay. So --

MS. RAY: The only way you drop out from the denominator is if you died.

MR. HACKBARTH: So when a patient dies, it can reduce the cost per beneficiary within that period.

MS. RAY: Right.

MR. HACKBARTH: But then they don't influence the subsequent period calculation.

MS. RAY: Right.

MR. HACKBARTH: Okay.

MR. GRADISON: There are two pilots, Case Study 3 and 4, which started quite a while ago. The Florida one was in 2011, and the other united one was between 2009 and 2012. Have these been incorporated? Have the results of those been incorporated in the ongoing way in which the Florida Blues and United managed these programs?

MS. RAY: So that's a good question. I can't speak for the Florida Blues or United. What I can tell you is Florida Blues, they are -- in addition to using the approach that we included in the paper, which was a prospective payment for a prostatectomy, they're also doing an oncology -- I would characterize it as an oncology shared savings program. So I think they are using a variety of approaches as well as United.

MR. GRADISON: Okay.

MS. RAY: Yeah.

MR. GRADISON: I'm not sure whether you are telling me that you know all that you would like to know about what they are doing. That's all right. I just wondered whether they've learned something that they have applied. That is really what I'm trying to -- perhaps you could look further into that, if you don't mind.

MS. RAY: Okay.

MR. GRADISON: This other thing, it's very minor, but at the top of page 2, there is a sentence which refers to the percentage of Medicare spending and the top ten and so forth. I have read this over and over. Can it both be 52 percent?

MS. RAY: It is. Yes. Yes, it is.

MR. GRADISON: Okay.

MS. RAY: But perhaps I should have taken it to the tenth digit because that's where the difference was.

MR. GRADISON: Oh, no, no, no. That's okay.

[Laughter.]

MS. RAY: I know. I got a lot of comments about that. It really is 52 percent.

MR. GRADISON: All right. I don't want to add to them. Thank you.

MR. HACKBARTH: Further clarifying questions? Mary, Jay, and Craig.

DR. NAYLOR: Two brief ones. On the 21 percent, in this study, 21 percent died in the first 180 days; is that right?

MS. RAY: 20 percent.

DR. NAYLOR: 20 percent.

MS. RAY: We updated the results after the paper.

DR. NAYLOR: Okay.

And on the earlier slide, 4 percent of spending was on home health and hospice; is that right?

MS. RAY: Yes.

DR. NAYLOR: The other, I thought this was great. I loved the case studies. I'm wondering whether or not beneficiary cost sharing was considered. There were effort sin these to improve processes of care for beneficiaries, but was beneficiary cost sharing given high cost sharing for these drugs part of the thinking around the bundled payment in any of them?

MS. RAY: I think beneficiary cost sharing --

DR. NAYLOR: [Speaking off microphone.]

MS. RAY: Not that we are aware of, no. The only way that I think beneficiary cost sharing was at least affected is in the case of United MD Anderson approach, which gives them one bill for the entire year of services, so it does simplify in that respect.

DR. CROSSON: Nancy, I have two questions. The first one, from the case studies that you looked at and maybe conversations you have had, do you get any sense about the degree of latitude or lack of latitude in the choice of drugs based upon whether or not providers or in the case studies were trying to adhere to national protocols?

MS. RAY: From the literature -- and we included

a small discussion of it -- the use of clinical pathways, at least among commercial payers, has well diffused.

Within the case studies themselves -- I know, for example, the Medicare case studies is requiring practices to report on the guideline that is being used?

MS. SMALLEY: Yeah. In most of the case studies, there was some element of considering clinical guidelines or adhering to some kind of pathway or something like that. I'm not sure if that gets at your question.

MR. HACKBARTH: Maybe I misunderstood, but I thought, I interpreted the discussion, description of Peter Bach's approach as saying that it was guideline-based, and so the bundle, the amount of the bundle is based on if you adhere to the guideline, whereas the Medicare approach, I think is based on average cost experience with oncology patients, and it's not specific to a guideline. Did I interpret that correctly?

MS. SMALLEY: Right. It's not specific to a pathway, but there is the quality monitoring for CMMI's model. There is a component of that where --

MR. HACKBARTH: Yeah. But the calculation of the bundle and whether you're saving money or not is based on

an average cost experience --

MS. SMALLEY: It's not based on a specific -- right.

MR. HACKBARTH: -- which is the way Medicare historically has determined prospective rates.

MS. SMALLEY: That's correct.

MR. HACKBARTH: But an alternative model -- and I think Peter Bach's is based on your cost would be X if you followed this guideline, which is the right way to provide oncology case.

Is this what you're getting at, Jay?

DR. CROSSON: Well, there is a policy question buried in here that I'm loathe to bring up in this Round 1.

MR. HACKBARTH: Well, we will applaud for your self-discipline and move on to Craig then.

DR. CROSSON: Wait. I have the same question.

[Laughter.]

DR. CROSSON: The second one, in the material we read, there was a discussion of the oncology medical home, the so-called Come Home Project. Are there -- and you didn't bring that up in the discussion here. Is there something to be learned there, or what do you think?

MS. RAY: I think there is something to be learned there. We are awaiting the formal evaluation of the demonstration. My understanding is that it is ending this year. It was a three-year demo.

When we talked to the folks at CMS, they said they applied some of what they learned from that demo into the latest demonstration, the oncology care model.

My understanding from reading about the Come Home medical home is that they believed that there was savings due to declines in the inpatient admissions and ED visits, and that they were able to -- because they stayed open later, patients came to the office instead of going to the ED or the hospital outpatient. And plus, they set up a phone triage system to help patients deal with symptoms or what have you. So I think there are important lessons that will be gained from that demo.

DR. SAMITT: Thanks, Nancy. Two quick questions for you. On this slide, I know the inclination is to look more at controllable costs or outpatient costs, but I do have a question about the inpatient. Is it possible to tease apart oncology-related avoidable admissions within this bucket versus those that are not?

MS. RAY: You know, I think that's something that we can look into doing for the fall.

DR. SAMITT: Because as we think about what's in the bundle or what's not --

MS. RAY: Right.

DR. SAMITT: -- you would think that could be included in the bundle, given that it may be under oncologist influence.

MS. RAY: Yeah.

DR. SAMITT: My second --

DR. MILLER: There is some complexity.

MS. RAY: Clearly, there is some complexity. I mean, that would not be an easy thing to do. We could begin to look at that this summer.

MR. HACKBARTH: So, Craig, for the non-physicians in the group, would it be an example of an identifiable, avoidable oncology-related admission?

DR. SAMITT: So, for example, it would be -- most oncology is outpatient. So if you think about a clinical protocol that avoids a nadir of disease-fighting status, the oncologist should be able to control that nadir through other types of drug regiments. So whether you give GSF

that would stimulate the growth of infection-fighting cells, that would be under an outpatient influence, and if the protocol wasn't sufficient to avoid that, a patient may need to be hospitalized with a low blood count, or other transfusion or other things that actually could be done to control the side effects of chemotherapy, that would be an outpatient-controlled effort, and an admission should be avoidable in certain instances.

DR. MILLER: And I just want to say, again, I think that was a very good example on how much information from claims data that we'll be able to go through and say avoidable or not. That's why I wanted to just put a flag out on the play and say we can definitely look at this. How deep we'd be able to get into something like that is what is making me a little nervous.

DR. SAMITT: It may be worth looking at. I'm not sure how hard it actually would be to tease apart avoidable versus not avoidable.

DR. MILLER: We can get some outside consultation on this, though.

DR. SAMITT: And at the end of the day, it may be so small, it may not be worth it to think about including

in the bundle, but it may be, at least to quantify, the distinction may be useful.

And then on Slide 7, in terms of the trigger event, when you talk about cancer diagnosis, could that be the diagnosis that is made by any clinician, so it could be that PCP's cancer diagnosis, or would you require it to be the oncologist's cancer diagnosis?

DR. MILLER: What would you like?

[Laughter.]

DR. MILLER: I think both Nancy and I are looking at each other and unclear how from a policy perspective you would want to do this, and that would be a question. And then from the claims analysis, we could probably try and tease out where these things are coming from and then put it back in front of you and then exactly people like you could say that makes sense or it doesn't make sense.

MR. HACKBARTH: Clarifying questions? Herb.

MR. KUHN: Yeah. Just one quick question, and it really has to do with the examples that you've shared of the various demonstrations, both private sector and CMS thus far.

In the evaluation of those, were they able to

differentiate the power of the incentives to drive down cost versus the fact that those in the demonstration were being observed, and therefore, their behaviors changed because of observational activity going on there? Do we know the difference between -- were the incentives powerful enough versus just the observation, or were the evaluation contractors able to do that?

MS. RAY: Help out, Katie.

Of the case studies that we included, there's only been one write-up evaluation, and that's the United where they continue paying fee-for-service, which is drop the drug payment to ASP plus zero.

Do you want to add?

MS. SMALLEY: Yeah. I guess the only thing I would add is that that evaluation, it was still kind of unclear, kind of the internal mechanics of what was driving costs, so I don't know --

MS. RAY: Right. Because recall with that approach, they found that total cost went down, but drug costs went up, and that was a little bit contrary to what they thought what would have happened. And they conclude in the paper it's not clear why it happened.

DR. COOMBS: So, in the paper on page 16, you give the case study for Blue Cross/Blue Shield, and with prostate cancer and radical prostatectomies. What I was interested in, this in conjunction with the pie chart on Slide 5, it's been said that a lot of the cost -- well, the revenue sharing between the Part B drugs and the professional fees are a balance between what's expected -- let's see. How can I say this? It's that the professional fees may be somewhat lower in comparison to other specialties in a similar area, and it's more compensated by the Part B.

So when you bundle it together, when you bundle the drugs and the professional fees together, is there a way that the bundling breaks out that it's more equitable in terms of professional fees for physicians? Because, you know, it may be that ASP plus six and you add the professional fees balances out in the end with other services. I'm not sure that the breakdown is not comparable to other services that use the more expensive drugs.

DR. MILLER: So maybe one more passthrough. So here's at least a couple of things that I'm hearing here.

An oncologist gets revenue from a drug and also gets a professional fee.

DR. COOMBS: Right.

DR. MILLER: And so part of your question seemed to be around that. And then it seemed to also be, when you bring in the other parts of the bundle, does that have -- and this is where I started to lose --

DR. COOMBS: Does the bundle address a more equitable kind of professional fee that does not tie in the payment for the drug Part B? In other words, it's --

DR. MILLER: Here's the question that I have, now that you said it. You're using the word "equitable." What do you mean when you say that?

DR. COOMBS: Well, I shouldn't say equitable, but is it similar to other specialties and their professional fees? I'm not sure what the professional fee looks like for oncology, for administration here versus what rheumatologists do, immunologists do with IVIG, what does it look like compared to those same specialties that give the high-cost drugs.

MR. HACKBARTH: Yeah. It's been a point of discussion in the past when oncology payments have been

discussed. Oncologists say, "Well, if we could make more money through the administration or the patient coordination, then we wouldn't be so dependent on income from the drugs," and so that's the tradeoff that you're talking about.

DR. COOMBS: Right.

MR. HACKBARTH: I don't know --

DR. COOMBS: Specifically with a bundle with the prostate cancer, it's more surgically based than it is administering agent. So it would be a different kind of bundle that you might create with a cancer that you're going to be more aggressive with surgery versus less aggressive.

MR. HACKBARTH: Yeah.

DR. COOMBS: It's going to look very different in terms of the different services on the pie chart.

MR. HACKBARTH: So to the extent that we use bundling in the potential additional income that oncologists could gain by their share of savings from low cost under the bundle, that would move them still a further step away from how most physicians gain their income. Most physicians, they provide a service, submit a code, and they

get paid for that. Oncologists' income would be based on their fees for administration plus some profit out of the drugs plus some profit by reducing hospital administration. If I'm understanding you correctly, that would make them even less like surgeons than they are today.

DR. COOMBS: Right. But if you were to subtract all of those and just go with what does it look like for just the professional fee alone --

DR. MILLER: Well, I mean, if you want to -- here is one way to reset this is if you want to think of this as a Round 1 kind of transaction, what we can definitely do is for specialties that you named and anyone else that you're interested in, kind of go through and show you the professional fee across the different specialties, and maybe that helps you get your head around the equity issue that you're looking at. So from a mechanical and a data point of view, we can come back with that kind of information.

I think the complex question that you'll immediately rejoin is if you want to make what you think is equitable, it's going to be different across different specialties, and part of their practice expenses and their

professional fees are all different for all the reasons that I won't bore you with and that you know well too. And then you will have the overlay of the bundle, and then you guys will have to come to a judgment of whether that's equitable and fair, but we can certainly put the basic numbers in front of you.

DR. COOMBS: And then the last thing is, looking at the CMMI and the various bundles, I wanted to ask this question. How much did they include shared decision-making in end-of-life care as a component of the quality indices?

MS. RAY: One of the requirements for participating in that demonstration will be providing patient navigation services, which I do believe includes some sort of shared decision-making.

Katie is going to track to see whether it's an explicit -- I'm not sure if it's an explicit quality measure, however. We can check, and we will get back to you on that, but they are required to provide patient navigation services.

MR. HACKBARTH: Okay. Continuing Round 1.

DR. REDBERG: Thanks very much. This was a really interesting chapter.

My clarifying questions were just the $11.7 billion is for all oncology drugs, correct, not just --

MS. RAY: The $11.7 billion is all Part B drugs, oncology and non-oncology. That's 2013, furnished in a physician's office and paid based on ASP. So oncology drugs represents about $6 billion of that, roughly.

DR. REDBERG: And that's for all oncology drugs?

MS. RAY: Yes.

DR. REDBERG: Do you have any data on what percentage of all spending is allocated to breast, colon, and lung cancer, which you had looked at in more detail?

MS. RAY: Of that, using 11.7 as the denominator, no, I don't. That, I don't --

DR. REDBERG: I'm just wondering what -- those are obviously the most common cancers, but I don't know if that drug spending is --

MS. RAY: Right. I could get back to you on that with something. Yeah. I don't have that here.

I mean, my understanding is that it's probably heavier in chemo than some other types of cancer, like prostate, for example. At least that's my understanding, but let me get back to you on that.

MR. ARMSTRONG: This hopefully is not a Round 2 question, but I was trying to just clarify: What is the problem that we're trying to solve? Is it this weird incentive that comes from ASP plus 6 percent and concerns that we're spending too much as a result of that? Is it just a very expensive course of care and, you know, highly risky and we want to feel like -- or create a payment policy that gives more control over that? We talk a lot about, particularly in these pilots or these case studies, the benefit that comes from better coordination of the different types of care, and, you know, kind of a view of outcomes.

And so when we get to the payment policies, it seems like we're going to need to be pretty clear about which of those problems are really most important for us to solve, and I just wonder if we had a point of view as we came into this.

MR. HACKBARTH: Can the answer be all of the above?

MR. ARMSTRONG: It could be [off microphone].

DR. MILLER: I'll give you my view and why this is in front of you. So go back several months -- and I

can't remember the specifics, but we had conversations about least costly alternative and the notion of trying to set, you know, in a sense a reference point type of policy. That was very much about drugs in Part B. We also had discussions about going back into ASP and asking about whether the categories in ASP were set up in such a way that you drove as much competition and reaching the average sales price.

There were reactions -- and, you know, I'm characterizing your comments, and so I'm trying to do my best here -- of like, well, you know, this is complicated because each of those instances kind of involve the government making a decision. Isn't there a way to try and get this decision much more in the hands of the clinician and a decision point between the clinician and the patient? And there was a specific mention -- I'm looking down at that end of the table to see if I get a nod -- of like could we think about bundling? I don't want to call anybody out or anything, but could we look at bundling? And so we went back and said, well, half of Part B is oncology. There's some motion out in the private sector where people are trying to bundle. We'll come back with

that.

This is going to be a constant dilemma for you guys. I'm going to just take the motion to get way -- or the opportunity to get way out of Round 1. There is this tension where, you know, the Commissioners want to be in kind of large -- I would characterize many of the Commissioners wanting to be in large population-based types of solutions, yet we live in a world that is still very spread out between fee-for-service and ACOs and MA, and we're going to have this constant tension of what do you want to do on the fee-for-service side and how do you -- if you want to encourage people into the other world, what do you do? And I feel like these conversations often come back to that kind of principal point. I'm done.

MR. HACKBARTH: And I think that was really well done, Mark, and that last point is, I think, important and there is this constant tension. I just want to really pound on your first point. I think, if I understand these different models, it's sort of exemplified in the models. The Bach approach, if I understand it correctly, says let's define what the right care is and have a payment system based on it as opposed to the traditional Medicare

prospective payment model and saying let's not prescribe what the right care is, let's look at the average cost and set a prospective payment based on that.

Having watched Medicare policy from a lot of vantage points for a lot of years, you know, my personal belief is it's very difficult for CMS to do the Bach approach and prescribe a pattern of care. And that to me is part of the appeal of this bundling. Let's decentralize the clinical decision about what's appropriate care but create a system where there's an incentive to economize where possible while also producing high quality. It's a decentralization. I just think that's, generally speaking, a much more effective way for Medicare to achieve these goals than trying to use the coverage process or a guideline specification process.

MR. ARMSTRONG: And I just was thinking that, well, if the real issue is we pay these providers to administer these drugs at ASP plus 6 and that creates faulty incentives and it's kind of unique, well, let's just change that.

MR. HACKBARTH: Yeah.

MR. ARMSTRONG: And that's part of the reason why

I was asking --

MR. HACKBARTH: Kathy was, I think, the person that Mark was alluding to.

MS. BUTO: Actually, I think the episode bundling was actually Jay's idea, but I think it is an important avenue to explore. When we were talking about LCA, we're really talking about drugs that are in a category where you've got multiple drugs that could compete potentially against an effectiveness guideline and a price could be set that way.

There's a lot of frustration around -- and we tend to kind of conflate these -- the new high-cost drugs. And so the question is: How do you go at an area of therapy where you sort of have a unique drug or maybe one or two drugs in a category? And it's very tough to go after innovative drugs unless you can do it in the context of let the practice figure out whether they need that drug or something that may already be available that may not produce the same benefits. And the bundle, at least in my view, is one way that you can provide that flexibility.

So I think it solves in a way a different problem, but it's the one that keeps coming up. Whenever

we talk about LCA, it's funny that the issue of the high-cost hep C drugs comes up, and yet I'm not sure that they lend themselves to LCA as well as they might lend themselves to something more like the Bach approach that's an evidence-based bundle, maybe a more limited bundle.

So I think it's worthy of our thinking about it. For one thing, it moves away from the government having to make very politicized decisions in this area. And it also tries to push more the notion of evidence-based practice. So I think that was the rationale behind the exploration.

I have to say, looking at these options and particularly the CMS model, you know, I'm a little baffled, but we can get to that in Round 2 because I'm not sure --

MR. HACKBARTH: I do think we need to be realistic that this isn't a panacea. So when, you know, a new drug comes out that has a very high price tag that would sort of swamp the bundle that's been created, you know, there will be controversy about, well, the bundle price is too low because it doesn't take into account this innovative new drug. So it doesn't make all problems go away by any stretch.

MS. UCCELLO: So I want to build off Mary's

question about the cost sharing. It's something I hadn't thought of, so I thank her for bringing this up. I want to make sure I understand this correctly.

So in MD Anderson, there's one bundled payment, and the cost sharing is based on that one cost, right? So, in effect, that means that some people are going to be paying more than they would have otherwise, and some less, if it were -- right? So I think as we move forward on this kind of thing -- and I would imagine that the broader the bundle, the bigger the variation could be compared to what they would have paid before.

MS. SMALLEY: Right. In the MD Anderson example also, they picked a very narrow, specific type of cancer. And so I think that, you know, the variation was less because MD Anderson has kind of been working on, you know, kind of streamlining that for a long time, and that's part of why they were able to do that prospective payment that way.

MS. RAY: And to be clear, they have eight bundles based on the treatment approaches, so that's another way that they are reducing the variation, I would imagine.

MS. UCCELLO: Right, but I think -- and I won't say this in Round 2, but I think as we move forward on this, it's important to kind of understand a little more about how beneficiary cost sharing will be affected and how the different designs may affect that differently.

DR. MILLER: The only thing to keep in mind in that is, depending on how you construct the bundle, if you keep a fee-for-service process running underneath, you know, sort of a shared savings, I'm not sure it's immediately true that the beneficiary gets it. And so that might be a design thing that you guys want to talk about in Round 2.

DR. HOADLEY: Yeah, I had some similar thoughts about cost sharing, which we can get back to in Round 2, but my specific question relative to that was on the CMMI demonstration, since that's an example that isn't bundled at the level of the drugs, right? So the cost sharing would still be done the way it is, and the shared savings would be separate. With the $160 monthly fee, would there be cost sharing attached to that?

MS. RAY: I don't think so.

DR. HOADLEY: Okay. And my other questions are

sort of tags on earlier questions. On Slide 6, you know, you said you can go back and look at sort of numbers, if you started the trigger event earlier at the diagnosis. Do you have a sense at this point of how much earlier the diagnosis tends to be than the first oncology?

MS. RAY: You know, I don't want to misspeak. Let me -- we can get back to you on that.

DR. HOADLEY: That's fair enough.

MS. RAY: Okay.

DR. HOADLEY: And on 5, I think Glenn asked about, you know, whether the pattern would be different for other kinds of cancer than the three you looked at. Is it different among these three? Have you looked at that? Would you get a similar pie chart for each of the three?

MS. RAY: I'd have to get back to you about whether it's a similar pie chart. Actually, it's down here. But what I can tell you is that the average cost per beneficiary for the 180 days is lowest for the breast cancer patients and is higher for the colon and lung cancer patients.

The other item to keep in mind is this does not include Part D.

DR. HOADLEY: Right.

MS. RAY: So that is something else that --

DR. HOADLEY: Breast cancer in particular would have Part D drugs.

MS. RAY: Part D drugs. And when I did look into Part D drugs, those patients -- the breast cancer patients did use more antineoplastics in terms of dollars, Part D dollars. But, again, I only looked at it after the first Part B drugs, so I don't know what was going on before the first Part B drug.

DR. HOADLEY: So it seems like it would be useful -- I mean, it's a lot of different cuts on the data, I realize.

MS. RAY: Right.

DR. HOADLEY: And you may not be able to give us every particular split we want, but it would be useful to be able to think about some of those other splits, and we may get more specific as we get into this. I'll leave my other things for Round 2.

MR. HACKBARTH: So just to follow up on that point about some types of cancer involving significant use of Part D drugs, you know, I think that would be an

important consideration in design. For sure you wouldn't want to create an incentive where because only Part B drugs are included in the bundle, there's a much heavier use of Part D drugs, some of which are going to be very expensive for patients because of specialty tiers and whatnot.

MR. THOMAS: Just two questions. First, did you look at the types of quality measures that were looked at in the various pilots? And were any of the quality measures around the coordination of care, kind of going back to Scott's point? Was there an improvement in coordination of care or patients' perception of coordination of care in any of the pilots?

MS. RAY: The United pilot is the only one that we have an evaluation for, and that one does not discuss that. They discussed that there was no change in survival and that patient admissions went down. There's lots of measures in the new CMMI oncology care model, which I expect after the five years we would hope to learn something about that.

MR. THOMAS: And then I know in the United it indicated that surgical intervention was part of the United bundle with MD Anderson. Are any of the others including

surgical intervention?

MS. RAY: The Blue Cross/Blue Shield of Florida one is based on the surgery for prostate cancer.

MR. THOMAS: And then CMMI, that's really kind of post-surgical intervention and really kind of focused on the medical oncology and radiation oncology --

MS. RAY: Right. For the CMMI, the trigger point is the chemotherapy administration. If the patient is managed only on, let's say, surgery and radiation oncology --

MR. THOMAS: Then --

MS. RAY: That's right.

MR. THOMAS: Okay. Thank you.

DR. CHRISTIANSON: Yeah, also on the CMMI, the way you wrote that up, it seemed like it's kind of more in the formative stages than -- yeah. So obviously one of the things that stands out is the 30-plus quality measures and seven domains, and the statement in your writeup that said that payment would be adjusted based on that. Do we know anything more about that? How much of the payment is at risk for adjustment based on those measures, and how might that work?

MS. SMALLEY: So the payment is from the shared savings component, is the payment that would be adjusted based on the quality metrics. So when you're comparing the actual expenditures to the benchmark target price, there's that 4 percent discount rate. And then if the actually expenditures fall below that, the practices are eligible for up to 100 percent of that difference, and that's based on the quality measures. So if they perform well in all of the quality measures, they could theoretically get all of the shared savings. And if they perform well in some and not others, that percentage would go down.

DR. CHRISTIANSON: So did I understand that 4 percent then is really the potential gain, or --

MS. RAY: The 4 percent, so every -- CMS will calculate a benchmark for every practice. From that benchmark they will subtract 4 percent. I guess that's supposed to be the government share. And so the difference between the practice's actual spending and the target, that would be the potential shared savings for the practice. And if the practice met 100 percent on its quality metrics, that practice would get 100 percent of the savings, between the target, which is the benchmark minus 4 percent on the

one-sided.

MR. HACKBARTH: And so it's the minimum savings ratio, to use the --

MS. RAY: Yes.

MR. HACKBARTH: -- ACO language, 4 percent if the minimum savings.

DR. CHRISTIANSON: All right. Thanks.

MR. HACKBARTH: Okay. We're ready for Round 2. Could you just help me think about the relative merits of narrow versus broad bundles? All other things being equal, you know, I would be inclined to go broader as opposed to narrower, of course, with appropriate boundaries on maximum risk and the like. Just talk about what the arguments are, pros and cons, on bundle size.

MS. RAY: Well, starting with the broad approach, a broader approach would give clinicians and practices more opportunity to affect other services: inpatient admissions, ED visits, hospital outpatient department visits. On the other hand, it could be more complex to put into effect a broader bundle if it affects multiple provider types.

On the other hand, the narrow approach, like the

Bach approach, just the oncology drugs and the administration, I mean, that's -- there's no opportunity for savings anywhere else.

MR. HACKBARTH: The United experience, which was surprising that the oncology drug spending went up and hospitalization and other services went down, really sort of caused me to think, well, a broader bundle really may make sense. You know, if there is a great new drug that comes in that can potentially reduce other types of utilization, you want clinicians to have both that incentive and that opportunity to shift the allocation of resources in oncology care. So I'd be interested to hear what other people think about that as we go through.

DR. REDBERG: Just to follow on that, I think there is an advantage to a broader bundle, because like a lot of things -- you know, there's a lot of different ways to treat the same cancer, prostate being one example, chemotherapy, radiation, or surgery. And there are a lot of studies indicating the results aren't very different, you know, for a lot of different cancers with different courses of treatment and what you get is sort of depending on who you see, you know, in your first encounter. And so

you wouldn't want to create perverse incentives to get care that was not necessarily the best outcome base, and that seems to me an advantage of the broader bundle.

MR. HACKBARTH: Others on this particular point?

DR. CROSSON: Yeah, I agree with that. I think, you know, experientially, as we heard from the United study, it was not just cost of hospitalization but total costs actually went down when drug spending went up. And I think what I heard Nancy say was that it's likely that the Come Home medical home project is going to show similar results. So for all the reasons that Nancy said, which is it gives the physician or other caregiver or team of caregivers --

DR. NAYLOR: He told me I could poke him.

[Laughter.]

DR. CROSSON: -- a broader opportunity to make tradeoffs and the like, which -- it also, you know, as I think Mark mentioned earlier, it's one of these opportunities that we have to kind of introduce into the more diverse marketplace of care the notion of care coordination, of working together in teams and accepting risk for the total cost of care.

There's one other point that I think is important to take into consideration, and it has to do with the fact that if we were to choose narrower bundles, we might very well find, you know, as it looks like as is already the case, that the latitude that exists in the choice of pharmaceutical agents is narrower than we might expect. And I think one of the reasons for that is a lot -- I think folks know this, but a lot of the oncology care that's delivered in the country is actually delivered on protocols that are established at NIH and other places, oncology groups that exist around the country. And there are some areas of latitude, but there's not complete latitude. And I think we would potentially have a risk -- or at least, you know, looking like we were doing something which could disincent physicians from signing up for research protocols if, in fact, there was a strong financial incentive to have more latitude in drug selection than was indicated if one signed up for a cooperative protocol.

So I just think -- I guess I'm thinking we need to be thoughtful about that, and maybe as we talk to more people in the oncology field, get a sense of how much latitude actually exists in the choice of administered

drugs, at least.

DR. NERENZ: I just wanted to speak directly in support of Jay's point, and I was going to make the same point, basically, that so much of oncology care is protocol driven that I think as we think about the design of bundles, we want to be clear about are we fundamentally thinking about choices among all sorts of varied drug treatments, and Jay's point would suggest, well, maybe not.

But on the other hand, we may be thinking about situations in which there are opportunities for care coordination, side effect prevention, unplanned admission, and my sense of the intent of this CMMI demo is that, more so than the choice of drug. I guess I'm -- another way of phrasing Jay's point.

DR. CROSSON: It's broad.

DR. NERENZ: Yeah. Broad, good.

MR. HACKBARTH: On this same point? Mary, Bill, is it on this point? Go ahead. Mary then Bill, and then I have --

DR. NAYLOR: I also really support a broad approach. I think Slide 4 or 5 tells really extraordinary stories. We have 60,000, I think, in this study, and

12,000 die within 180 days. So if you were to try to uncover what was going on in inpatient, you might be watching a lot of people at end of life, bearing high costs, et cetera. Only 4 percent, or about $1,600 of the $41,000, is being spent on home care and hospice.

So if that goal is reducing total Medicare spending at the same time that we're ensuring some higher quality of life, I think we have to have a very broad opportunity here to really adjust care as patients' needs are changing.

DR. HALL: Listening to the discussion so far, I think what we're talking about is what do you mean by this term we use over and over again, "oncology services." What is this bundle looking like? I think Scott raised some issues, and I think Warner as well. Are these just discrete episodes of administration of a drug, or is there a broader way to look at this?

And I think here's another opportunity for us to sort of think large. My crystal ball is no better than yours, but it's probable that in the future of Medicare that any of us in the room here who reach that age have at least a third or a 50 percent chance of either having had

or will have cancer. Increasingly, cancer is a chronic disease, much in the same way as heart disease is.

So I think the model is saying oncology services are someone makes the diagnosis, we give them a drug, and let's make sure that we're using protocols, that we have some cost effectiveness in this drug.

And then when that ends, we put them on hospice. That's a model that's been used traditionally, but I don't think that's the model of the future, so what does that really mean, I guess. Well, to me, it means that there are a lot of issues about oncology services that have to do with, I guess what Mary was referring to and others in the room, of what we might say quality of life. There are some credible stories that sort of pass among physician groups, largely oncologists.

A good example would be that parents of children with cancer will say they don't have to ask the doctor when their child is getting worse, and what's the clue? The health care personnel don't talk to them anymore, or stories about a woman who writes a great deal who had a patient in psychotherapy. She was a physician, and this woman said that she had decided with her oncologist to take

a holiday from specific drug treatment. She said, "I'm not sure this is how I want to live the rest of my life," and when she asked when the next appointment would be, the oncologist told her, "Well, there's no reason for you to see me again because we're not delivering some kind of a drug or something." So she decided to undergo chemotherapy just so that she could have the reassurance of being with a physician that was knowledgeable and that had developed a relationship with her.

So I think CMMI demonstration may give us some clues as to what we really mean by oncology services, so I really would think we should look very carefully into a broader approach. It's going to affect a lot of us, if it hasn't already.

MR. KUHN: I'm also kind of in the camp of the broader bundle, and I think that's worth looking at for a couple of reasons. One is a little bit of what Bill was talking about, and I'm trying to think about more the patient experience in this effort.

So one is, if it's a narrow bundle, does it create some arbitrary decision-making that might be made out there, and if it's a broader bundle, does it give the

physician more latitude to design the treatment plan and the activities that are related to that?

Then also, I think about -- and maybe the clinicians here can help me think this through -- is does a broader bundle also help deal better with symptom management that folks who are going through chemotherapy are dealing with, whether it's the issues of pain, fatigue, and nausea, and the administration of antiemetics to deal with some of those and those issues out there. And I just think a broader bundle maybe gives them more latitude to manage some of that symptom management, which is so critical for those that are going through chemotherapy.

DR. COOMBS: Thank you very much.

Jay brings up a very good point, and I thank you for that because I was thinking along those lines. Breast cancer treatment at various stages is pretty much predictable throughout the country.

One of the things I thought about is the broad bundle is -- I think I favor that in some scenarios. Narrow bundles might be more advantageous when you have something like prostate cancer. The patient goes in, gets their prostate done, and that's it. And they're fine.

They go back to work, and they do their thing. Whereas, as you've mentioned some of the other interventions after chemotherapy is delivered, during chemotherapy, actually require a lot of supportive treatment, whether it's supportive treatment because of symptomatology and even pain management, and so I think when you have someone who has a considerable amount of pain, nausea, and vomiting, those kind of things can be handled with a broad system, a broad approach to bundling. So I think I would favor that.

One of the things, since the mic is on, I was thinking along the lines of how do you look at quality and efficiency and mortality in such a fluctuating group of diagnoses -- colon cancer, lung cancer, and breast cancer, all thrown into one bundle. Someplace like MD Anderson has the capacity to do some really innovative things in terms of looking at data, looking at cost, and becoming efficient and saying, "In our hands, the national data says this in terms of survival at the given states, and our data indicates this as well." And a smaller entity or a low-volume provider might not have that same capacity.

So I think the benchmarks for quality and efficiency, looking at mortality, with the smaller

providers, it's going to be very different than in MD Anderson, and it's almost like it's a high volume -- and we've always had this discussion about providers -- high volume, are they better performers because of the mere fact that they are high volume and they see a lot more and they do a lot more. Naturally, we cannot provide a high-volume provider like an MD Anderson in every single ZIP code in the country, but I think we have to take into consideration that Medicare beneficiaries are not all in the MD Anderson region.

MR. ARMSTRONG: Just briefly, I mean, you know I'm a big bundle kind of a guy. In fact, I think go bigger, go home as far as bundles are concerned.

[Laughter.]

MR. ARMSTRONG: In fact, I think for the record, we ought to say bundles -- the best bundle for dealing with our issues here is one that prevents cancer to begin with, right? Okay, so I said that.

Now, having said that, I'm actually not sure I agree with what we've been saying. First, what are we trying to solve? Is it we're spending too much on drugs because the payment at ASP plus six creates the wrong

incentives? There's a solution to that that has nothing to with bundles, it seems to me.

Second, I'd like to understand. Walmart is buying bundles for orthopedic surgeries. This is happening around bundles that actually are remarkably predictable, and there's very little variation in the outcomes. It seems oncology care is kind of the opposite of that, and so I would just before we leap to the conclusion ask, Is this really the best place first? Is a bundle the best solution to the problem we're trying to deal with? And second, is this really -- if we're going to use bundles, is this the best population of patients for us to apply those bundles to?

To be honest, there's a lot about protocols and so forth in oncology I have no knowledge about, and so I could be wrong about that. But I just think it was worth challenging our assumptions about that as we launch into this evaluation.

DR. MILLER: You also made a comment yesterday when we were talking about Part D and we were going through all the risk stuff, and you made a similar comment, right?

[Laughter.]

DR. MILLER: My batting average today, I want to apologize to Kathy. I think she must have been sitting next to Jay that day.

I thought you said yesterday -- and maybe I should take this offline because what I thought you were saying yesterday was we're spending all this time on risk and trying to think about the risk structure of D, but is there -- I almost asked yesterday. You said is there almost like a bigger question we should be asking about how we think about how we pay for drugs here. I almost took your comment that way, and I wonder if you're saying that in so many words again here today.

Maybe you and I ought to talk a little bit because I feel like there is a consistency in your comments that are trying to push in a different direction. I'd like to make sure I follow that.

MR. HACKBARTH: Let me just give my own personal, very specific answer to your question. I don't see this as a way of fixing problems that may exist with the ASP payment system. This is a different conversation, and that's in part why my instinct -- not a conclusion, but an instinct -- is a broader bundle is better. It isn't just

about how much we pay for drugs. It's also about which drugs are appropriate and which other services are appropriate in high-quality oncology care. So I don't think that we are taking on something big and complicated to solve a narrow problem like, "Oh, we don't like the ASP system." I think the objectives here are much broader than that.

MR. ARMSTRONG: Yeah. And, Mark, we should take that offline. If it was brilliant, then I'll take credit for it, but I don't really remember what it was.

[Laughter.]

DR. REDBERG: Otherwise, it was Kathy.

MR. ARMSTRONG: I do think in oncology, to the degree I know about this, there are very expensive and not so expensive surgical versus drug versus radiation alternatives, and to me, that's much more around engaging in an evidence-driven evaluation of the alternatives, and to the degree we create a payment policy that inspires that -- and that really makes sense to me -- I'm not sure that's a bundle, necessarily.

But if that's really what we're trying to solve, then I'm all for it. I actually thought we got into this

through our concern about the specific Part B drug spending.

MR. HACKBARTH: This has been helpful, Scott.

As you probably noticed, we're over time, and I want to get through everybody who's had their hands up and been waiting patiently, and then I also want to allow a very brief opportunity to sort of open up -- have people identify other big issues that they would like Nancy and Katelyn to explore in the next round. So my targeting for finishing is at ten o'clock. If you would help me get there, I would appreciate it.

Jack.

DR. HOADLEY: I'll try to be brief.

I mean, in some ways, I think the counter-issue that we might have been trying to solve isn't so much the ASP issue, but the least costly alternative issue, which you can almost think of as kind of a mini bundle, and it's a mini bundle in the sense that it's among drugs that are very similar, so it's not really the way we normally think of bundles. It's saying if there's a couple drugs -- it's almost like generic and non-generic level of similarity or one step above that.

On the one hand, I'm a little like Scott. On the one hand, I find it very appealing to think about this, the broader, because -- I mean, Craig talked about some of the things that you might do to keep somebody out of the hospital that had more to do with the ancillary services, the ancillary drugs, dealing with symptoms and side effects and keeping you healthy. Given the chemotherapy and the idea that those would be in the bundle makes a lot of sense because they should be part of the overall package, even to the point of thinking about what keeps people in and out of hospitals and all that.

The problem is I have trouble thinking about -- so if we're at this level of a large bundle and we're setting some kind of an average price on it, what are we now averaging across? Are we averaging across such a huge array that you really actually create the other kinds of incentives? If I think about how sort of the DRG world thinks, you start to then subdivide. So we've got the bundle for treating breast cancer, okay, but now how many comorbid conditions, and what stage cancer? Maybe that's the right way to go; maybe not.

Some of this has to do with choices. Do we want

the choice of treatment when things might be very diverse in cost to be overdriven by -- I mean, it becomes just as cost driven if the incentives are we have one average, and so if you pick the expensive one, you're really going to lose a lot of money. Pick the cheap one; you're really going to make a lot of money. That's as much of a financial thing as saying, "Okay. We've got it exactly lined up with the cost of each service that has their own profit margins and so forth on it."

Then eventually, I want to see us linking this back to cost sharing, which would be the issue I'd put up in sort of last thing, and if the cost share is now attached to the bundle now, the patient has their own set of odd incentives. They are going to pay the same amount, regardless of treatment. That could be good, but they don't have the same options. If they want to choose a very conservative treatment, they are still paying part of the cost of other people's less conservative treatment.

MR. HACKBARTH: Those are really important points, Jack. So if you go broad, then that means either you have to have really good risk adjustment, so that you're not really being unfair or have real confidence that

the people receiving the bundles have large numbers, and there's going to be lots of averaging ongoing, which is probably not true in this case.

Then you try to counteract problems with potential risk selection and people being unfairly burdened by narrowing and doing clinically homogeneous subgroups, and you've got to find an appropriate balance. Breadth has strengths, but it also brings with it potential problems and need for risk adjustment and all that stuff. These are not simple choices.

DR. HOADLEY: And risk adjustment would mean something very different inside this world.

MR. HACKBARTH: Exactly.

DR. HOADLEY: We're not talking about age --

MR. HACKBARTH: Right.

DR. HOADLEY: -- and people with certain comorbid conditions and things. We'd be talking about risk adjustment within sort of a cancer context.

MR. HACKBARTH: Exactly. Really good points.

Warner, you had your hand up?

Let me just see the hands of people who want to get in here. Okay. so I have Warner, Kathy, Dave, Craig,

and Rita.

Who wants to open up a completely new issue?

DR. REDBERG: Let him speak first.

MR. HACKBARTH: Okay.

DR. HOADLEY: I could say that I've raised the cost sharing kind of link and not say it again.

MR. HACKBARTH: Okay.

Warner.

MR. THOMAS: I would just say one. I think the concept is a good one. Two comments I would make.

One, I think having a broader bundle in certain instances where you look at a surgical intervention where there could be, going back to the point made earlier, that that could or could not be an option, I think could make some sense, although I think there's some concerns there.

I do think going down the road, if we have a bundle around chemo and radiation and the treatment protocols here, I think would be very helpful because I think there are incentives there that are not necessarily aligned. So I would say that that would be a positive direction to go. I would actually say in certain diagnoses, a broader bundle could make some sense, but I

would say in almost all diagnoses, going the direction of a chemoradiation, that treatment regimen could be very helpful.

MS. BUTO: I was going to say that I think a combination of what Scott was talking about, a little bit about the broad bundle, is something that could be further pursued. In other words, the model would actually start with kind of the United One approach, which is the assessment team, and then the bundles could be broad but then focused on whether it's going to be radiation oncology.

And by the way, I think there already was a radiation oncology bundle, a weekly management fee, that when I was there we created to allow more flexibility for the practice. So there have been tiny efforts to try to bundle some of this to make it more rational for the provider groups.

So you could then create a broader bundle that would include aftercare, hospitalization, et cetera, plus, say, radiation oncology or chemotherapy.

Two points I wanted to make are I really hope that in thinking about the bundling of an oncology drug

approach that Part D would be included. I mean, I just think your point, Glenn, that what isn't in, you're going to create some kind of a distortion that you can't even anticipate yet.

And the other thing I would just mention -- and this might be a follow-up -- is that I think it's important for us to think about, a little bit, the criteria that an agency like CMS would use in trying to assess what opportunities to go after.

If you could look at those areas of treatment, it could also be surgery. It could be hip replacement, whatever, but oncology is clearly one of them where the agency ought to be developing different approaches, criteria, and then some notion of the ability of an agency to actually implement this thing.

I think some of this gets so complicated. I looked at the CMMI demonstration, and I thought 5 years, all these different quality measures, one-sided risk. At the end of the day, I think some of us could imagine what the result is going to be. It looks like it's going to be more cost with the per, the monthly fee, and one-sided risk.

So I just feel like if you go at it from the point of view of where do we think the opportunities are to do a better job of providing incentives, and then what are the approaches that will actually improve the overall outcome. And this approach, focusing just on oncology drugs, may not be the right one, but I just thought a combination of Scott's approach and then a broader bundle around that assessment was a better way to think about it.

DR. NERENZ: Okay. Two very quick things. If this is going to come back around to us, the latter part of the chapter on pathways, I'd appreciate it if you could clarify more for us what the difference there is, if any, between pathway, protocol, and guideline. I couldn't tell in reading it exactly what that was, and since we've said that cancer care is characterized by being protocol-driven, I'd be really interested in knowing is there an additional concept under the word "pathway"? So future.

And the other thing is that although -- on the CMMI demo, although I think it's very appropriate to have it on the list here of bundling demos, I don't think that is its essence. To me, its essence is more practice transformation and care coordination. So if I was going to

say what kind of a demo is it, I'd say it's more of a p kc transformation and care coordination demo than it is a bundling demo. It's got features of both, but what's dominant I --

DR. SAMITT: I recognize why we jumped in immediately to the size of the bundle as the first topic, although I actually wonder whether that question is the last question to answer, because as I was trying to go through it, very similar to Scott, I tend to be a big bundle guy. But as I thought about that in this particular instance, I have some concerns.

So, for example, how would we address the stinting issue? I'd be a little worried that the risk of stinting increases as the bundles get bigger. If you're dealing with a discrete episode and you say I'm going to look at the costs of drugs, when you prescribe drugs in a particular cancer diagnosis, stinting is less likely. But if someone's diagnosed with cancer and now there's this big bundle that you could spend or not spend, I would be worried.

Likewise, the other factor in here that's not considered is who's accountable for the bundle. So with

colon cancer, is it the PCP that's accountable? Because they could direct the patient in a variety of different directions. Is the colorectal surgeon accountable? Is it the oncologist that's accountable? And so yet again, I think you'd have to figure out who would be accountable for the bundle, and the bigger the bundle, the more vague it gets.

So I would argue when we come back to this, we should think about some of the other detailed elements perhaps first, and it may guide us to the right decision about how to think of the size of the bundle.

DR. REDBERG: First, just to respond to the last part of Craig's and then give you my big picture thing. So I could say I'm a big bundling kind of gal.

[Laughter.]

DR. REDBERG: And I understand, of course, the stinting issue, but I think we should also recognize how much harm there is in the current system with the incentive to overtreat, because we have a lot of harm -- a lot -- from overtreatment, and people say, you know, there could be -- but right now I think if you want to talk -- you know, we want to get to the right place, we're kind of over

here in terms of incentives for the opposite of stinting, you know, for overtreating people where they're really suffering at the end of life and not getting good care, as Mary alluded to.

And so I think, you know, getting back to our goals, our goal is always to focus on the Medicare beneficiary and how can we deliver the best care. And to me the best care is, you know, the best treatment and then still compassionate care, and that's I think where we really have a lot of room for improvement in oncology care, because we know that a lot of people get very toxic and disfiguring and unpleasant treatments at the end of life without any benefit. And there are a lot of different reasons for that.

So, you know, to me we do best when we stick to the evidence of treatment that improves outcomes because then -- and that's why I think an outcome focus in whatever bundle or approach we take is really important.

And I wanted to point out a few trends in oncology in particular. One is that the FDA has been moving towards approving oncology drugs in particular on the basis of markers and surrogate outcomes, progression-

free survival, and even biomarkers. The problem is, as we saw, for example, with Avastin, that you can approve something on the basis of progression-free survival and say we're going to wait for the studies, which then take longer to look if there's a benefit on survival, even when there is not a benefit on survival, and so now you're giving a very toxic and very expensive drug with no improvement in survival. Practice patterns are established and don't change, and that is just one example. And that is happening more and more where drugs, very expensive and very toxic drugs, are being approved on surrogate markers without evidence of benefit on survival.

Then I'm not an expert on oncology guidelines, but like a lot of other guidelines, I know that they're not always based on evidence. They're also based on expert opinion, which may not -- and I've heard criticism of the NCCN because a lot of the guideline panels there have a lot of people with conflicts of interest, and that -- because anything -- and that was particularly pointed out to me because I think anything listed at NCCN Medicare has to pay for, but it's not always a very strong evidence base, and there are other reasons that -- and so I think, you know,

if we're looking at how we want to spend the Medicare money on treatments that improve patient care, I think we need to look really closely at the evidence that we're looking at, and then, again, you know, if we were going to focus on outcomes, I think that's a better way to do it.

And then just lastly -- and I think Mary alluded to this -- we know that a lot of people are getting care at the end of life that is really futile and toxic in oncology and that people would do better with sooner referrals to palliative care and hospice treatment. And I think that it's important to recognize that in the bundles. You know, that example that Bill mentioned I hear about a lot where patients at end of life feel like their doctors don't talk to them anymore when they don't have treatments for lots of different reasons. I think we become very focused in medicine on giving, you know, medical treatment or surgical treatment and feel like we've failed if we can't offer -- and I think, you know, we really need to start focusing on the fact that we have jobs as physicians even if we don't have drugs that we can give patients, and that it's not a failure of medicine or a physician to say, you know, "I'm very sorry, but you are at the end of life, but I am still

here for you. I am still your doctor, and I will still continue to see you and care for you," because I think it is very hurtful and harmful. And I would hope that, you know, we'll keep that in mind as well when we -- because I think it's certainly not the only reason, but right now the system tremendously rewards doing, you know, expensive treatments that often don't help patients at the end of life instead of focusing on patient goals, which is really a more compassionate death often at home, not in the hospital.

DR. CHRISTIANSON: Just a real -- I think this is consistent with what Dave said and certainly with what Rita said. The bundling discussion tends to, it seems to me, start with the notion that can we construct a bundle that will save Medicare money without having a detrimental effect on quality. And that's certainly consistent with the value-based purchasing notion of getting more for the Medicare dollar.

So my question for you two, to think about, not to answer now, is: If instead we viewed value-based purchasing as using the same amount of money to get better outcomes -- and I think this is consistent with what Rita's

saying -- in terms of quality of life and in terms of clinical quality, would our discussion be different? Would we be thinking about bundling and what the issues are different if we -- if the goal of bundling was framed as improving quality of life, improving quality of care for Medicare beneficiaries for the same amount of money, which, again, is value-based purchasing. We're getting more for the dollar. So that's just a sort of general question for you to think about, I think.

MR. HACKBARTH: Okay. Thank you, Nancy and Katelyn. I'm sure we'll hear much more of this topic in the future.

So our last session is on synchronizing Medicare policy across payment models.

Julie, are you leading? Whenever you're ready.

DR. LEE: Good morning. This morning, we continue our discussion on synchronizing Medicare policy across payment models.

In your mailing materials, you have a draft chapter for the June report containing our analyses from January and March and new materials on beneficiary decisionmaking and coding adjustment. We'll try to pull

all the parts together in today's presentation.

We'll begin with a review of previous presentations and go over key design issues raised during past discussions. There are additional issues for you to consider, including those related to policy design, beneficiary decisionmaking, and coding adjustment.

In January, we showed that no one model is uniformly less costly to the program in all markets. MA and ACOs tend to have lower program spending than fee-for-service in high service use areas; whereas, fee-for-service tends to have lower spending than MA in low service use areas.

For example, when we looked at the relative program spending for MA, ACOs, and fee-for-service in markets where all three models exists, we saw that MA and ACOs had lower program spending compared with fee-for-service in markets that are in the highest quartile in service use.

In March, we shifted our focus to the beneficiary perspective and looked at three illustrative examples for calculating beneficiary premiums.

For simplicity, we went through the examples for

two market areas, Portland and Miami, which are at the tails of the distribution in terms of average fee-for-service spending. We added Columbus, Ohio, as a market area whose fee-for-service spending is roughly in the middle of the distribution.

This table summarizes the three illustrative examples from last month. Just to review, the three examples were defined by two policy levers: one, how the base premium was set, whether nationally or locally; and, two, which Medicare option that base premium paid for, whether fee-for-service Medicare everywhere or "lower of" fee-for-service or MA in each market. In other words, either fee-for-service Medicare or reference MA plan, whichever was lower cost.

As you can see in the table, beneficiary premiums can vary across different options for Medicare coverage and also across the market areas. For instance, if you look at the second example, where a nationally set base premium pays for the lower of fee-for-service or MA, the base premium of $101 buys fee-for-service in Portland; whereas, it buys the MA in Columbus and Miami. If beneficiaries choose other options, then they might have to pay more.

In other words, beneficiaries pay more for MA in Portland, but they pay more for fee-for-service in Columbus and Miami.

Throughout our examples, there were two numbers that had a direct effect on beneficiaries' premiums: the average fee-for-service spending and the median MA plan bid.

Especially under the second and third examples, where the base premium paid for the lower of fee-for-service or MA, the difference between these two numbers was added to the base premium if the beneficiary chose a higher-cost option.

This slide shows the distribution of the difference between fee-for-service spending and the median MA bid. To the left of 0, the median MA bid is higher than average fee-for-service, and to the right of 0, fee-for-service is higher than the median bid. For example, about 2 percent of beneficiaries are in market areas where the median MA bid is higher than fee-for-service spending by $100 or more. And about 28 percent of beneficiaries are in markets where fee-for-service spending is higher than the median MA bid by $100 or more.

By definition, this distribution is going to look very different with a different reference bid. We picked the median MA bid for illustration in our examples. But there's a distribution of MA bids to choose from in many market areas.

Moreover, our analysis used plan bids from the current MA program, which is different from the three examples we looked at. Under different rules, MA plans are likely to bid differently and make different decisions regarding whether to enter or exit a particular market. Consequently, some markets might not have MA plans.

Let's briefly review where we began our discussion. No one payment model is uniformly less costly to the Medicare program in all markets. So we want to create financial incentives for beneficiaries to choose efficient models.

In this policy context, our illustrative examples of calculating beneficiary premiums highlight two key design questions.

The first question is: How is the base premium set? Nationally or locally? This question is about the variation in spending across market areas.

Under the second example, the premium does not vary across areas; whereas, under the third example, the premium varies with local fee-for-service spending.

Another way to think about this question is:

Is it fair for beneficiaries in high-spending areas to pay higher premiums for the same basic benefit? Or is it fair for beneficiaries in low-spending areas to cross-subsidize beneficiaries in high-spending areas? These questions reflect the exchange between Glenn and Kate about equity at last month's meeting.

The second design question is: Which Medicare option does the base premium pay for? Fee-for-service Medicare or the lower of fee-for-service or MA? This question is about the variation in spending that exists across different Medicare options within an area.

Put another way, is it fair for beneficiaries to pay the same premium regardless of whether they choose a higher-cost option or a lower-cost option? Is it fair for taxpayers to shoulder higher program spending when beneficiaries choose a higher-cost option?

Depending on how you answer these two questions, there might be potential savings in program spending, and

if so, how to share potential savings between the program and the beneficiary.

In addition, there are other design issues we haven't addressed. We briefly mention just a few.

First, what kind of a transition or phase-in would a new policy require, such as specifying a number of years for the phase-in or a cap on the dollar change in premiums?

Second, would it apply to all beneficiaries or only those who are newly eligible? In particular, how would low-income beneficiaries be affected?

Lastly, would it apply to all markets or those meeting a certain threshold of conditions, such as a minimum level of MA enrollment rate?

Our discussions so far have focused on using premiums to create financial incentives for beneficiaries to choose efficient models for Medicare coverage.

If they have to pay higher premiums for fee-for-service in areas like Miami, they would have to trade off the perceived benefits of fee-for-service with MA that is lower cost, and vice versa in places like Portland.

But to design incentives that can change people's

behavior, we need to consider how beneficiaries actually make decisions and respond to incentives.

Here are some key points to keep in mind about how beneficiaries make decisions?

First, beneficiaries make a basic tradeoff between being able to choose any doctor or keep their current doctors versus cost. The findings from our interviews and focus groups suggest that those who can afford Medigap premiums would choose traditional fee-for-service plus Medigap, while those who might be more worried about costs and more willing to accept a limited network of providers would choose MA.

And beneficiaries make these tradeoffs with the information they have. Although they have more information available to them than ever before, they may not necessarily have a better understanding of the Medicare program. In fact, the increased volume of information may contribute to the confusion because they might not always open or read mail sent from CMS. Health insurance counselors say that this is true regardless of the education level and income of the individual.

So in order to simplify information and

decisionmaking, beneficiaries look for sources that are easy and convenient. In particular, many of them rely on other "human" sources, such as family, friends, brokers, agents for MA plans.

But simply providing information about Medicare would not guarantee that they are going to make the best choices for themselves. There are several reasons why beneficiaries can get overwhelmed by choice.

First, our ability to understand and use health insurance -- Medicare included -- may be limited simply because health insurance is a complex product. It requires people to consider multiple dimensions simultaneously, it's filled with unfamiliar terminology, and it requires a high level of numeracy to make informed judgments. Moreover, people have different preferences and needs for health care, which can be also uncertain and unpredictable.

Second, the psychology literature suggests that too few or too many choices are not desirable. In fact, people may prefer fewer choices to reduce the likelihood of making a poor choice or the sense of regret about their choice.

When it's difficult to choose among options,

people may focus on variables that are simply easier to measure, like premium cost, and ignore other salient factors, or rely on recommendations from others, or just simply stick with the same insurance coverage year after year, even when better options are available. Such strategies or shortcuts, however, may lead to eliminating options they may actually prefer more.

Finally, the nature of how choices are presented, described, and framed can influence people's decisionmaking. Because we are prone to systematic biases, our decisions are quite sensitive to the context in which we make them, whether it's the order in which choices are arrayed or the words used to describe and frame them. Therefore, designing processes around people's choice could take these biases into account and minimize them, if possible.

Now Carlos will discuss issues related to coding adjustment.

MR. ZARABOZO: Our discussion of synchronization involves comparisons of the cost of one payment model versus another in different market areas. In making the comparisons between MA and fee-for-service and in showing

numerical examples, we use costs for an average beneficiary, or what is referred to as a beneficiary with a risk score of 1.0. Part of what determines a person's risk score is the diagnoses that they have. A risk score for a very sick beneficiary would be much higher than the risk score for healthier person.

If we are to make valid comparisons of costs between MA and fee-for-service, then the coding of diagnoses affecting expenditures needs to be consistent between the two sectors to make sure that a 1.0 average is determined the same way in each sector, fee-for-service and MA.

Similarly, in comparing quality between MA and fee-for-service, we want to make sure that in each sector coding of diagnoses is consistent and comparable between the two sectors. Coding adjustments may be necessary to ensure consistency and accuracy.

Currently, consistent coding is important in Medicare Advantage because of the way plans are paid. Payments vary depending on a beneficiary's health status and demographic factors. Each Medicare beneficiary is assigned a risk score based on diagnoses and demographics.

The risk score tells you the relative cost in fee-for-service Medicare of providing care to a given beneficiary compared to the average beneficiary. The diagnoses, and the relative costs of serving a person with a given disease, are determined from the claims data of fee-for-service Medicare and the Medicare program expenditures represented by those claims.

The risk scores of MA beneficiaries are based on the diagnosis information submitted by MA plans. What happens in MA is that plans code more completely or more intensively than is the practice in fee-for-service Medicare, so there is a mismatch between the risk score that a person has as an MA enrollee and the risk score the same person would have in fee-for-service Medicare. Because under the current risk adjustment system the appropriate payment, if you will, should be based on the risk score the person would have had in fee-for-service, there is a coding adjustment to the MA risk scores to make the coding consistent between MA and fee-for-service.

In the same way that there is currently a coding adjustment for MA, in order to have accurate bids that represent what the bid is for a person of average health

(or a 1.0 risk score), a coding adjustment would be necessary to compare a 1.0 bid from an MA plan to a 1.0 level of expenditures in fee-for-service Medicare. The same would be true of comparisons to ACO per capita costs if it was found that ACOs coded more intensively.

Coding intensity also affects the evaluation of quality. Some quality measures are risk-adjusted based on diagnoses. For example, sicker beneficiaries are more likely to have hospital readmissions, and this likelihood of readmission is taken into account in determining whether a hospital or plan performs well on readmission measures. For quality measures that are not risk-adjusted, more intensive coding may increase the universe of beneficiaries included for a particular measure, with a possible mismatch between one sector and another that affects the apparent performance on quality measures.

Today in MA the coding adjustment for payment purposes is an across-the-board uniform coding adjustment across all plans. As we pointed out in the material you received, a question to consider is whether there should be varying coding adjustments by geographic area or by plan.

DR. LEE: Here's the key design questions from

several slides ago. The first is the question of national versus local base premium. This question follows the conversation Glenn and Kate had last month about whether Medicare beneficiaries should pay the same base premium or not.

The next question is: Which Medicare options should the base premium pay for? And if there are potential savings in program spending, how to share them between the program and the beneficiary.

And, lastly, we're interested in your ideas and guidance on possible next steps on this topic.

MR. HACKBARTH: Thank you. This has been really good, a terrific analysis and very thought-provoking.

Just a question about terminology. We use the term "fee-for-service" to describe traditional Medicare, and I wonder whether that is, in fact, the right term to use. Increasingly, Medicare, traditional Medicare, is not fee-for-service. We're talking about bundling and all sorts of things that actually are moves away from fee-for-service yet would still be encompassed in this alternative.

You know, I wonder what the right label is. I don't know. "Traditional Medicare"? "The government-

managed insurance plan"? I don't know. But it seems to me that fee-for-service may not be really the correct descriptor.

In fact, for me, the most important characteristic of traditional Medicare for this purpose is that it is the free choice of provider plan. You pay a single premium, national premium, and you are guaranteed, you have an entitlement to a free choice of provider, regardless of how much that provider costs compared to other alternatives. And so I don't have an answer for this question, but I do think referring to it as "fee-for-service" is increasingly inept, and maybe it would be good to find another term. "Traditional Medicare" has been the best that I can come up with, but you can tell why I'm not in the advertising business.

[Laughter.]

MR. HACKBARTH: So Round 1 clarifying questions.

DR. SAMITT: So my questions are mostly about the coding section, the clarification. So in the materials, the chapter that you had sent around, you talk about the 5.16 adjustment versus the need for a further reduction by 3 percent. Can you elaborate on sort of how you did that

analysis and, you know, if coding is essentially used to really help us to distinguish between the complexities of two different populations, what alternative methodology are we using to determine whether 5 percent versus 2 percent is the right adjustment?

MR. ZARABOZO: And I'm going to invite Scott to answer that question.

[Pause.]

DR. HARRISON: So we had taken samples of beneficiaries who had been in MA for different periods of time and been in fee-for-service for the same amount of time, looked at their baselines, and saw that the coding -- the risk scores grew faster when you were in Medicare Advantage. And so we weighted then by how long everybody had been in MA, and the MA population probably is about -- has coding about 8 percent higher than what the people would have had if they had stayed in fee-for-service.

DR. SAMITT: So, in essence, comparing the trajectory of a patient who -- a like patient who would have stayed in fee-for-service versus the patient who switched --

DR. HARRISON: Right.

MR. HACKBARTH: -- from fee-for-service to Medicare Advantage and the delta between essentially the curves, the trends.

DR. HARRISON: Correct.

DR. SAMITT: Okay. Thank you.

The second question I have is on Slide 4, the all-market comparison, 105 percent to 100 percent. Does that 105 percent take into account all payments, including additional payments for risk adjustment? Risk adjustment is already factored into that distinction?

DR. HARRISON: Yes.

DR. SAMITT: Okay. Thank you.

MR. HACKBARTH: Clarifying questions?

DR. COOMBS: Has there been any attempt to look at proxies for risks that are not necessarily correlated with coding? You know, you present in the presentation about more intensely coded -- coding in the MA plans as compared to the fee-for-service. Has there been any other kind of proxies of, for instance, the percentage of dialysis patients under MA plans versus non-MA plans? I mean, I don't know if that's something that can be done.

MR. ZARABOZO: Well, I don't know whether -- what

the percentage of dialysis patients in each would tell you about the respective coding.

DR. COOMBS: Yeah, just in terms of the level -- if you were to take a very sick population -- and it doesn't have to be dialysis patients; it could be anything -- to see what the difference might be reflected in actual sick patients being cared for in MA plans. I mean, if you have a tool, an instrument that doesn't level the playing fields in terms of one being more intensely coded, which is directly tied into risk adjustment, which is directly tied into quality, and directly tied into reimbursements on one side, and the fee-for-service is lacking on coding, I mean, maybe more robust EHRs, EMR on one side versus the other. But if you have a differential and your ability to assess one over the other, it begs the question that the reimbursements or whatever, the quality bonuses are going to be different.

MR. ZARABOZO: Well, one thing, for example, that -- it's an article that we cited by Kronick and Welch was looking at the one diagnosis in particular, they said there appears to be higher coding in the MA plans is major depression. And so the HCC categories, there are only two

mental health categories: major depression and schizophrenia. So they looked at the relative prevalence between MA and fee-for-service, and you have a higher prevalence of major depression, which kind of indicates it might be more coding, because there's nothing below major depression that feeds into the HCC risk assessment that can be used for coding purposes.

So there are differences in that -- I mean, that's one way to judge are there differences in the coding.

MS. UCCELLO: So I have a few questions.

On Table 8 in the mailing materials, you show a huge difference in the risk score in plans in Miami versus Portland, and so I was wondering if you could just expand on -- if there's anything other than the obvious one on here.

MR. ZARABOZO: One thing, I mean the fee-for-service risk score, too, is very different between Miami --

MS. UCCELLO: Okay, that's --

MR. ZARABOZO: Yeah, yeah, that's -- yeah.

MS. UCCELLO: Okay. How much MA bid variation is there within an area? You talked about using the median.

Is there a lot? Is there a little?

DR. LEE: Actually, there's a lot. So if you are looking at minimum to maximum in each area, that is very wide range. Now that they -- distribution is quite lumpy. You know, you can have -- the difference between the lowest and second lowest could be quite big. So that I think varies from area to area.

MS. UCCELLO: And it might come into play when we think about how we define this lower of kind of thing. I haven't worked it all out in my head yet, but -- and, finally, on Slide 9, you talk about the additional design issue of whether this is done in all market areas or only those that have above a certain threshold. I assume there you're talking about MA enrollment above a certain threshold? So are there -- this would matter most, I imagine, in places where the MA would be the lower. Are there any -- and those would presumably be in the high-cost fee-for-service areas. Are there high-cost fee-for-service areas that don't have robust MA enrollment? How big of a deal is this?

MR. ZARABOZO: Okay. We had previously mentioned Cook. I haven't checked lately in Cook County, but Cook

County was an example of, you know, high expenditures and not very much MA penetration there. But I haven't, again, looked lately at what the --

MS. UCCELLO: Okay. So this is a real issue as opposed to just theoretical.

MR. THOMAS: I think this was in a previous report, but did we -- for the markets that have all three types of options, what percentage of those markets is fee-for-service the cheaper option?

MR. ZARABOZO: Fee-for-service, traditional Medicare --

MR. THOMAS: Traditional Medicare.

MR. ZARABOZO: Without ACO --

MR. THOMAS: Correct.

MR. ZARABOZO: -- probably -- I don't have the number right here, but almost a third. In many cases it's almost a third, but I want to say that the differential isn't a lot. So, you know, if you look at like the ACO/fee-for-service differential, sometimes one's a little higher, sometimes one's a little lower, and part of that could just be the random variation that we see. And I think the better figure is the one where we look at the

average differences that show on average in those high-spending markets you can save about 2 percent with MA or ACOs, and in the high-spending areas generally the government is spending more on -- at least on MA. Excuse me. The low-spending areas the government is spending more.

MR. HACKBARTH: Continuing Round 1.

MR. GRADISON: Looking at page 9 in the meeting brief, necessarily you've -- well, maybe not necessarily, but you compared 2015 data because it's available with 2013 data for ACOs, which is the most recently available data. It would seem to me that you might be better off to use 2013 for all of them rather than -- because you're using it for analytical purposes anyway, and you recognize in the document, the last sentence on page 9, that this could change as more recent data -- that is, that data for 2015 rather than 2013 -- becomes available for ACOs. It's sort of a presentation thing, but it kind of jarred me to think we're comparing two different years and trying to draw observations out of that data. So that's just a comment.

DR. CROSSON: Yeah, so, Carlos, when you're talking about the coding thing, I heard you say something

about wanting to watch in the future ACO coding. I wasn't sure I understood that because virtually or perhaps all ACO models currently in existence and even planned, with the possible exception of one of the Vanguard models maybe, it's basically just fee-for-service payment. So why would ACO coding -- why would you think ACO coding would be different from fee-for-service coding?

DR. MILLER: Probably two things driving -- I'm sorry. I think it's probably two things driving that comment, and we had this very direct conversation in getting the presentation together.

One is that if you -- and we took you through in the Executive Session a bit of CMS' next generation and ACO, and there's some looking down the road to using, you know, regional benchmarks, moving off of historical, and at a very simple level. The reason that they started off with historical benchmarks is you don't have to risk-adjust them because that's your population, now you have to beat your history.

To the extent that they start to move off of that, then you have to think about, well, do you have to risk-adjust this baseline if you're going to hold them to

something that's more market or regional oriented. That's the first thought.

And the second thought, it's the same thought, but we're talking about synchronization here and thinking about a baseline or a benchmark that cuts across ACOs, MA, potentially fee-for-service, depending on how you think about the beneficiary. And there, again, it would probably mean we have to introduce a risk adjustment type of process to that, which then might mean that the ACOs have the same incentive as an MA.

Did I get that about right?

MR. ZARABOZO: Yes, and in some of the ACO models, like the NextGen that David talked about, they are going to have risk adjustment based on HCCs, so you'll get a bigger benchmark up to a certain degree if you have higher risk scores, meaning those ACO doctors have an incentive to code.

DR. CROSSON: So it is related to the projection of what the Vanguard -- at least that's what they were calling it -- or newer ACO models might look like. That's the substance of it.

DR. MILLER: That's the near term, and the

longer-term [off microphone] would be what you as a Commission decide about what you want to do on synchronization. It would decidedly be an issue there, and I think that's why--

MR. ZARABOZO: The other point is the quality point, which is if you're going to be measuring quality and comparing fee-for-service and ACOs and MA, you know, for bonus purposes or whatever, you would like to have consistent coding.

MR. HACKBARTH: Okay. Any other clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Let's move to Round 2, and, Mark, would you frame this issue? Put up the slide that has the various options for how to set the basis of comparison, you know, the one that Kate referred to.

DR. MILLER: Okay. So the last time we talked about this, Kate very methodically went through a number of the issues and sort of talked out with all of you about how she was trying to understand. And what you'll remember -- and she was sitting over around where Alice is sitting -- is she came down and she and Glenn had an exchange, and we

thought that this might be a good place to bring you back to. And it kind of comes down to two issues, and let's see if I can do this in a way that's clear, as clear as Cori was yesterday, for example.

One is imagine the average fee-for-service per beneficiary in the country is $9,000 or $10,000 per person, okay? And you know that that varies across the country. You know it's almost two times that in Miami, and you know it's 20, 30 percent less than that in Portland.

One very strict way to ask the question is: Should the beneficiary premium in that instance be the same in all of those markets? Miami has much more fee-for-service spending; Portland has somewhat less than average. Why does the beneficiary pay the same premium? And you could define "equity" two different ways, and this is the exchange that Glenn and Kate were having, which is, well, it's higher in Miami so the beneficiary should pay a higher premium; or the reverse, which is, no, the beneficiary should pay the same premium because they don't have any control over what happens in Miami. And that's a very intense, philosophical issue that has to be thought through.

Now, I told the story from just a straight fee-for-service point of view because I think it's simpler, but when you get into this where are we going to set the premium and how are we going to set the premium, it comes back into play. Do you adjust the premium for underlying differences in the cost of the market?

The second question is also very significant, which is, What does that premium buy? So let's just say you settled out -- and I hate to speak for her not being here, but I think Kate was of the mind you pay the same premium throughout the country, but that -- and that's one way you could resolve it, and Kate and Glenn were talking.

But the second question is: What does it buy? So, currently, that premium buys you twice as much fee-for-service in Miami and, you know, 20 percent less fee-for-service in Portland. And one of these options says you can still get -- and that's the top option. At a national premium you can get fee-for-service in any market. And notice in the top tranche there, there's a flat premium, 101, and then notice the third row of that premium, the federal contribution is quite different. So, in Miami, it's a thousand bucks, and in Portland it's 500.

The other way you could do it -- and I would draw your attention to the second tranche, third row. You could say the federal contribution will not go all the way up to fee-for-service; it will only go up to the lower of. And notice in Miami you're no longer paying $1,000 in federal contribution; you're paying $600. And then the beneficiary's premium is a function of what choice they make.

And so one more time -- I'm afraid I've made this more complicated. One more time. Should the premium vary by geographic variation and cost for the -- or expenditure for the beneficiary?

Second question: What does that premium buy in your market, the lower of fee-for-service or managed care? And very different consequences for the government's contribution, and then what the beneficiary pays out-of-pocket depending on what choice they make.

And I guess the very last sentence I'll say -- well, I'm done.

DR. NERENZ: Just a technical question on that point. When we talk about premium in this discussion, our base premium, we're really talking about Part B premium,

right? Because there is no Part A premium. Is that a fair statement? And then if we are, the variation across region is not all Part B variation. In fact, it's a lot of post-acute whatnot.

So I'm just trying to think through with you, Mark, that, you know, we talk about what it buys you. Well, we're sort of loading a bunch of other variation on to and up/down in a Part B premium, so you're buying something other than Part B with the higher Part B premium. My question -- does that even matter? Is that even important?

DR. MILLER: I'll step out first on this, but I would like some close support here. And I don't feel like I'm getting the real engaged looks from you that I want to get. I'm getting a lot of looking off like this.

[Laughter.]

DR. MILLER: Okay. What I would say is for the purposes of this exercise, I wouldn't spend a lot of time thinking about that. What I would say is it's really a question of to purchase the Medicare benefit, where would you set -- how would you set the premium and what would that premium buy? For purposes of this conversation,

that's what I would say.

To make my point about geographic variation, yeah, it really is about the Part B premium, because that's what's going on right now. But I think I ought to ask you for the purposes of this discussion to step back from that a little bit and say, you know, what premium would the beneficiary pay to get their Medicare. You know, these kinds of ideas involve lots of, if you want to put it this way, back-room discussions of then what do you do about, you know, the purchase and the choice of Medicare, and does it remain an A-B split type of situation?

For the exercise, I would say try and get above that. But that's my take.

DR. SAMITT: So I'm trying to get my head around it, and I looked at this through two different dimensions. One is if I'm a beneficiary in any of these markets, if I want to purchase the lowest-cost alternative, it will be identical in each of these scenarios. So if I'm in Miami-Dade, then I'm always, if I want to pay less, going to pick the MA option in any of these three scenarios. And the same would be true of Columbus and Portland.

So I guess the question is: How material would

these options be and having beneficiaries make a choice if a choice is around price?

MR. HACKBARTH: And so I think that's a really important issue, and you'll recall -- it's really unfortunate that Kate isn't here today because she's so good on these issues. But, you know, there is, as I understand it from Kate, some literature on behavioral economics that people respond differently to different types of incentives. The incentives can be the same in dollar terms, but people respond much differently to a loss than they do to a potential gain. They may respond differently to cash as opposed to added benefits. And so I think all of those are issues in terms of how you might structure the choice.

DR. MILLER: And can I just do one thing? I'm going to go to the board, which is going to frustrate her, but I'm going to do this anyway, because I think this is really important, and I want people to get [off microphone].

DR. SAMITT: So kind of this notion of a withhold versus a bonus, and the psychological impact of whether it would be a positive or negative impact.

MR. HACKBARTH: And Bill Gradison has often made this point. The difference between cash versus added benefits may evoke a different beneficiary response as well. So if it was still that, you know, you had Scenario 1 but plans were writing checks to beneficiaries who enrolled in MA in Miami as opposed to the beneficiaries getting gym memberships and, you know, vision care -- I think GAO has done some analysis suggesting that some of the added benefits are not heavily used, and presumably they're not highly -- therefore, are not highly valued by beneficiaries. But in the calculations, you know, they count for, oh, this is your reward for joining an MA plan in Miami.

DR. SAMITT: So my second issue, which may be a less important dimension, is if I'm a Medicare beneficiary and health care costs are so important to me that I am willing to move cities to find the best environment, the next way to look at this -- and it may be more of sort of an equality issue in terms of beneficiaries in City A versus City B -- is that in the first scenario, relative to the various metropolitan areas, I'm going to pay the most for my health care in Portland. In the second scenario, it

doesn't really matter. It's equal regardless of what market I'm in. And the third scenario, I'm going to pay the most if I'm in Miami-Dade.

So I couldn't help but think of some of the GPSI discussions we've had and sort of the cost-of-living differences, and does that factor into -- from a Medicare beneficiary and a cost-sharing standpoint, if you're going to live in sort of higher-cost or higher economically driven markets, should you costs be higher in those markets for health care? So that would be the second dimension that I looked at when I saw this grid.

DR. MILLER: The only thing I would say about that -- and I want a nod here or a nod, a shake -- is they should think of these numbers are certainly risk adjusted, like a one-point over risk for the purposes of this exercise. Should they be thinking of these as wage-adjusted numbers? Because these are not -- is that -- no. Okay. So then --

MR. HACKBARTH: Okay. I have Warner and Jack, and we'll come back up this way. Warner.

MR. THOMAS: I don't know if this is more of a question or remark just around how we should look at this -

- or to the team here, but the thing about this, it looks like in 70 -- roughly 70 percent of the markets, the ACO or Medicare Advantage model is more cost effective. Is that correct? And in the 30 percent, that the models are relatively close? Is that accurate?

DR. STENSLAND: That's in the ballpark. I think the ACO and the fee-for-service are maybe the lower cost models, you're saying, in maybe two-thirds, and they are just a little bit lower cost in those. And I think the MA is a little more spread out in that it's maybe generally close, a fair amount more expensive in some markets like Portland, and then there's just a couple markets where it really saves you a lot of money, like in Miami.

MR. THOMAS: I guess the question I ask myself is that, with the right incentives, could the ACO and MA model be a more cost-effective model in all markets? We keep talking around the issues of bundles and incentives and all that sort of thing, and I know we talk a lot about ACOs. This is kind of looking at all-in, and the question I ask myself, What would have to happen in those markets where it's not the more cost effective to get it there? And then what sort of incentives should be put in place to try to

steer or try to incent beneficiaries into those models?

MR. HACKBARTH: Warner, I think that there are a couple, at least a couple variables here. There are some markets where there are relatively few providers, rural areas and the like, where I think it's difficult for Medicare Advantage plans to operate without subsidies for Medicare because they have very little leverage with providers. They can't really play one provider off against another. So there are sort of market structure issues for at least some segment of the country.

The other thing that is happening in places like Portland is the utilization rates are very low, and to the extent that Medicare Advantage succeeds by changing patterns of care, it's just a lot tougher to be beat the benchmark in Portland or in Seattle than it is in a high-utilization area like Miami.

So I'm not sure that it's necessarily true that in a place like Portland, where MA plans prosper and we have high MA enrollment in Portland, that it's because there have been subsidies. We pay more in Portland for Medicare beneficiaries to go into private plans than we do in traditional Medicare. Traditional Medicare is very

efficient in Portland because the utilization, the base utilization rate is very low, and it's always going to -- on a level playing field, it's always going to be tough for MA to succeed. Right now, it succeeds through subsidies, to be real blunt.

MR. THOMAS: Right.

So I would totally agree with that. The question I would ask is in that situation where you have a low utilizing fee-for-service market, would the right kind of ACO structure incentive -- I'll just take Seattle. So in Seattle, if you have low utilization, my guess is in Scott's model, with what he has from an integrated model, they're going to be able to, I believe, probably outperform a traditional unorganized fee-for-service model, if not every time, many times, especially with the right incentives and over time with the right coordination and what not.

I kind of come back to -- I understand you are always going to have a rural market where maybe the model just doesn't work or it's a very fragmented system, but I'm also of the belief -- and I think we ought to be challenging ourselves to think about end markets like

Portland that have low utilization, which is great, there's probably still opportunity, if you have the right model in place with the providers to do even better than they're doing today in a relatively unorganized, traditional fee-for-service model.

DR. HOADLEY: So I've got two kinds of comments. One is trying to think about picking up from what Mark's response to Dave's question of sort of framing this the right way. So I completely agree that we don't want to complicate this framing with the fact that the premium is on the Part B side. I think that makes sense to try to jump a step above that, but it may also make sense that we should be framing this without the complication of the negative number up here or the fact that there's this benefits versus cash kind of complication, that in a sense, we ought to be thinking if this was all just done in pure dollar premium tradeoffs, so that even if it meant artificially shifting the numbers, so we don't see a negative number, or we just think of a negative number in some way that ignores the fact that it may come in benefits versus cash, that we might also want to not have the complexities of the wage differences.

Some of these, I'm not quite sure what you would do empirically or how we would do it, but the fact that there are cost-of-living differences partly embedded in this is a complexity that kind of distracts from the core question I think we're trying to answer, and even this issue of the sort of underlying fact that the MA numbers are based on bids which have built in it these subsidies, because of where we stand, even at a point in time in a transition to full ACA changes and some of that kind of stuff. So should we be trying to pull those subsidies out so we're actually looking at the core question?

That's just some thoughts on -- I mean, I think the point is we really want to frame this as if these distractions were in the way, what's the right mix of incentives?

MR. HACKBARTH: So it's not clear to me how Medicare's subsidies that happen through the Medicare Advantage payment system affect the bidding process, which is our best estimate of plan cost.

One of the most striking parts of this analysis to me was how little variation there is in the MA low bid, geographically. You see the fee-for-service cost. You

have a two-fold-plus variation, and the MA bids between Miami and Portland, pretty doggone close.

DR. HOADLEY: So is it the case that in the way we've done these numbers that we really are looking at bids before we take into account benchmarks?

DR. LEE: They are bids. So it's supposed to be plan's estimate of the cost of providing A and B benefit.

DR. HOADLEY: Right.

DR. LEE: However, their bidding strategy --

DR. HOADLEY: Strategy.

DR. LEE: -- seems to be against the MA benchmarks, and so that's why the correlation is very strong to MA benchmarks.

DR. HOADLEY: So I misspoke a little --

MR. HACKBARTH: I'm sorry, Jack.

So just to elaborate on that, what correlation, Julie, are you referring to?

DR. LEE: So the correlation between bids and MA benchmarks is much stronger than correlation between bids and fee-for-service spending. If you want to look at fee-for-service spending as a kind of environment, you know, the cost of A/B benefit, that correlation is actually quite

small.

DR. HOADLEY: In theory, people are bidding truly based on their cost, but in reality, the bid acknowledges that there is a benchmark going on in the market, and naturally, you're going to bid somewhat differently. Either it's your incentive to change your cost, which is one way to think of it, or it's an actual bidding behavior that means your bids are not exactly your cost.

MR. HACKBARTH: Yeah. Okay.

DR. MILLER: I would say -- well, go ahead.

DR. HOADLEY: Well, if you want to comment on that, I was going to go on and say so my view of this is if -- sort of putting all those distractions aside, I still have difficulty with the notion that beneficiaries who choose a fee-for-service or traditional Medicare, because I do like the notion that we should be changing the terminology -- beneficiaries that choose traditional Medicare are paying for something that's differing geographically that is not changing what their purchasing is as a package of services. It may change the average cost. So some cases, it's the physician practices or the hospital costs are simply higher in their markets, whether

for wage reasons or for competition market reasons, or that others in their region are getting -- demanding and getting or being given more services than I would necessarily get if I'm the consumer in that market.

So I go back to that notion that I'm not real comfortable with the idea that I have to go in and pay for a higher price just because of where I live. It might mean I want to move to another area, and of course, that's not really a practical choice in most cases. So that's kind of where I come back is trying to think about what's the right kind of equity, and I see it on the Part D side where you don't have -- it seems like there's even less logic for the geographic -- but it's there, and so we do in fact have the result that we're putting in sort of scenario two and three in Part D where people are paying a higher price for the same bundle of drugs for the same set of prescriptions, not because the drugs cost more, but because something about behavior about prescribing or something in their state, in their market, just based on where they live.

MR. HACKBARTH: Isn't that what happens to the rest of America?

DR. HOADLEY: Maybe, but do we have to -- if that

is not a good result --

MR. HACKBARTH: Cori.

MS. UCCELLO: This isn't going to be coherent, so I'm going to need a translator.

MR. HACKBARTH: You have points from yesterday.

MS. UCCELLO: Okay. I can carry them over.

[Laughter.]

MS. UCCELLO: So this kind of builds off the last things that Jack was saying, but I seem to recall a thread from last month's conversation that when we were thinking about paying differently for the different areas because they have higher or lower cost, one of the things to think about is would charging those higher costs lead -- put pressure on provider behavior, and I seem to recall that the thought around that was maybe not, but I think we need to bring that back in.

It's reasonable to really seriously consider charging those different costs by area if we think that those will lead to, at least in the high-cost areas, lower utilization or lower prices.

DR. MILLER: That was very good, Cori. Really coming along.

When that thread occurred in the meeting last time, what I thought Glenn said --

MR. HACKBARTH: Go ahead.

DR. MILLER: All right, but you can jump in here and do your thing.

I think what Glenn was saying at that point -- because I kind of remember this thread too -- is, again, look at your second tranche, look at Miami. You have that $509 payment that the beneficiary might have to pay to be in fee-for-service. The beneficiary says, "I'm not going to do this. I'm going to go to a managed care plan." The physician in Miami sees their patient shifting from fee-for-service to a managed care plan and says, "Wait a minute. What's going on here? What do I need to do?" And I think this is the point that you're driving at. If providers start to see their business shift, does it put back pressure on the fee-for-service crowd to change their style?

And I think you said something.

MR. HACKBARTH: Yeah. And this is the mechanism behind the spillover theory, that in fact there has been some empirical research suggesting that there are

spillovers from MA enrollment into fee-for-service expenditure levels, and Kate mentioned that at the last meeting.

Scott.

MR. ARMSTRONG: I just would start by saying this focus that we've had on synchronizing payment between MA and fee-for-service and ACO, I think is a really important agenda, and I also, for the record, agree MA should cost less than fee-for-service. So we should be moving in that direction.

But what's been really interesting to me is this highlight now that this analysis has given to this incredible variation in the cost of the program by virtue simply of different geographic markets, not demographics, not anything else.

And while I am really sympathetic to the impact on the beneficiary and higher out-of-pocket cost in different markets, I like the idea that there would be a real different out-of-pocket cost between MA and fee-for-service in different markets.

I guess I would take it -- and so I'm okay with that. I would take it one step further and just say to me,

it's the third line, the federal contribution on that top category that is the big issue that jumps out for me.

And I know it's a little off topic, but I just wonder. We spend so much time confronting the different payment between hospital outpatient and physician office practice for like services, and we have a really clear policy position on that. We spent a lot of time looking at the least costly -- paying at the least costly alternative for drugs or for other alternatives. Why don't we work up some indignation over how dramatically different we're paying in different markets for basically the same service as a program? To me, that's not for today, but that's an issue that I think, if we did some quick math, offers spectacular impact on future expense trends for the Medicare program if we were to take it on.

So it's a little off topic, but, boy, this analysis to me offers a real bright light on an issue that I think will be very worthy for us to take on in the year.

MR. HACKBARTH: To me, options 2 and 3 and the fact that you have much less variation in MA bids than you have in fee-for-service cost suggests that if you want to move towards less geographic variation, this is one

mechanism that may help do that.

MR. ARMSTRONG: Yeah. I guess the point I was making was that -- so the whole lever is moving, then, the issue into choices the beneficiary has, and they look like pretty good choices to me. But I would just ask, Is there more that we can do?

I mean, we really -- most of our attention is on payment policy to providers, and these are scenarios that don't differentiate our payment policy to providers. I mean, I don't know what that looks like, but why are we not expending a discount off of what we normally would pay for people who practice in Dade County, as an example?

MR. HACKBARTH: When we move away from traditional fee-for-service towards various sorts of bundled payment systems, I would hope that over time, that would lead to some compression of geographic differences because I think that part of what's going on here is that in some parts of the country, there is a much stronger culture of taking advantage of the financial incentives in fee-for-service than in other parts of the country.

If you change those fee-for-service incentives, you may also see some compression, so that may be a benefit

of moving towards bundles.

Okay. I have Kathy and Jay and then Craig again, Warner. Anybody else want to get in here? We've got 20 minutes or so left.

MS. BUTO: Okay. I will try to be brief.

DR. SAMITT: A question about Scott's --

MR. HACKBARTH: Sure. Sure.

DR. SAMITT: I just have a clarifying question about the math, now that I hear Scott speak, because my understanding is this federal contribution amount or this over-$1,000 amount in Miami-Dade is inclusive of a risk adjustment payment, that when you back out, the complexity of illness in Miami-Dade versus Portland, that number drops to the 700-some-odd range. And yet this methodology, including the discount in the MA premium looks like it goes against -- I'm not articulating this well. I feel like Cori now. It looks like it goes against the fee-for-service amount as opposed to the backed-out bidding amount for the MA plan. So that's the piece that's confusing to me, that aren't these federal contribution differences, especially in the beginning -- doesn't that represent the fact that there's different risk adjustment levels in these

various markets, or no?

DR. LEE: All the numbers are for risk score 1.0.

DR. SAMITT: All of the numbers?

DR. LEE: Yes.

DR. SAMITT: In the third column, for example, in the third tranche?

DR. LEE: Uh-huh.

DR. SAMITT: Great. Thank you very much.

MS. BUTO: Well, I'll try to be brief. I was kind of going in the same direction as Scott. I think what we haven't really settled on and we need to come back to at some point is what our goal is here. Is our goal to guarantee fee-for-service at the same rate premium to every beneficiary in the country, or is our goal to try to look at the federal contribution and say what's inequitable, to use someone else's term -- how should the government be paying for these services around the country?

That's why I think Example 1 cries out for making that choice because that's the one where, clearly, the choice is driven by -- it's going to cost the beneficiary the same everywhere in the country, and I would like to see us really give serious consideration to that assumption

because I think that's going to continue to drive -- if you look at the Miami column again and the over-$1,000 federal contribution, the government is continuing to subsidize a certain level. Even if it's a great saving to go to the managed care planning, you're getting a lot more service, is potentially affordable with that kind of a federal contribution.

To me, it's inherently inequitable because it drives a much richer package, even if it tries to be more efficient, between fee-for-service and Medicare Advantage. So I think we have to get to that point of saying what drives -- what's our first principle here in terms of what we'd like to see the premium drive, if you will.

MR. HACKBARTH: Let's see. Who else do I have? Jay, I think I have you.

DR. CROSSON: Yeah. I have been struggling with this since we first discussed it almost a year ago. I think for the same reason that Kathy just said -- which definition of equity are we pursuing, and which one do we think is the most important?

One of the problems I think that I have -- and I've seen it now several times as we look at this -- is,

quite honestly, thinking about Miami-Dade, because Miami-Dade is not just at one end of the Gaussian distribution. It's clearly an outlier, and so it drives numbers that we're staring at there like the federal contribution is over $1,000 compared to about half.

I almost would wonder, as we think about this, as we get more towards practical choices, that we kind of put that out of our mind because maybe that has to be dealt differently with some sort of capping or something like that.

But when we start thinking about things like which mix of choices of equity we're going to make and we start looking at numbers and we start thinking about feasibility and acceptability to beneficiaries and actually getting there, that we deal with numbers -- and maybe part of this is adjusting these for regional input costs, because that's another sense -- that's another issue of equity. If I happen to live in Miami or New York or San Francisco because that's where my job is, is it my responsibility then to pay more for Medicare when I've put in the same amount of money as everyone else over my career, or should I be paying at a national kind of level?

If we were to back out -- and I know Jack talked about it as a complexity, but if we were in the future, if we sort of back out that piece and just say we are going to adjust for regional input cost, not regional utilization or any of this stuff that's being driven by inappropriate care, but just the input cost, and we take out the outlier and we look more at, say, from the 25th percentile to the 75th percentile and we start looking at numbers and we get a sense of the tradeoffs and the political, even feasibility of that, maybe we'll have an easier time thinking about the tradeoffs.

DR. MILLER: I think that was all very well put.

I think the notion of adjusting for the input prices makes a lot of sense in terms of equity. You will still see a lot of geographic variation, and I know you know that because a lot of it is utilization. As David said, a lot of it is post-acute care, but I think at a technical level, you're probably right.

Then the other thing I would just get you to return your attention to, because I know you don't have anything else to do, is the portion of the paper where in response to your comments the last time, we tried to show

you the distribution, and it's absolutely true that Miami is a huge outlier, and a lot more of these decisions are -- there's a lot within the $100 range, but there are a fair proportion that are beyond the $100 range. We as staff and you as Commissioners -- take a look at that table because it does start to move in that direction, and we'll try and think about how to come back and display it in a way that gives you a better sense of that.

MR. THOMAS: I'm kind of off this topic in a little different direction, but something I would like to see around synchronization was brought up at the end of the chapter, and I think it could be accelerated, quite frankly, is the synchronization around quality metrics because, frankly, it's a major issue. It's very different amongst the different paying mechanisms.

I know there's a lot of complexities about what we're talking about here and a lot to be considered, but I think on the quality side, something that could be accelerated and simplified much quicker.

MR. HACKBARTH: I feel like I'm missing one other person at least. Somebody else have a comment?

[No response.]

MR. HACKBARTH: Okay. Let me just then make one final observation. I think this analytic approach is really helpful in provoking thought about what the issues are, and this has been a good discussion.

Still another way to look at this from my perspective is in terms of fairness, and I've talked to Jack and Cori about this at some length. I know this is complicated, and there aren't clear right answers to it. But as the father of two 20-somethings and as I'm about to go into Medicare myself pretty soon, I've been thinking a lot about how fair this system is to younger people. Increasingly, we have a system for non-Medicare beneficiaries in America where free choice of provider is not the norm; in fact, it's almost nonexistent. Even among large employers with the most generals health plans, the base plan is a preferred provider organization. It has a network, and you pay more to go out of network.

Increasingly, health benefits, even in large employers, high-deductible plans are increasingly common. Increasingly, employers are moving towards defining contribution arrangements where basically the employer says, "We're going to pay this amount," often keyed to a

low-cost option, and if you want a richer option, you pay more.

These same principles are embodied in the Affordable Care Act. We tie the contributions to a relatively low-cost plans, and if you want the gold plan, you pay additional money out of pocket.

So those are the principles that increasingly guide health care for everybody else in America, including struggling young families that have lots of health care bills of their own, and they may not have very generous health care coverage, and they have college expenses. And it's really going to be people like me who have an entitlement, pay my $100-some a month, and so long as I've been in Part A-covered employment, I get free choice of provider. I get to stay in that, even if there are dramatically lower cost options in my community, and my kids pay for it, and that's not what they've got. So to me, there's a whole ethical dimension here about is this system fundamentally a fair one, or should we think about redefining the entitlement for Medicare beneficiaries? The entitlement is into a health care system like the rest of the country has, and I feel particularly strongly about

this because I think the likelihood that my children are going to have Medicare in the same terms that it's offered to me, given the demographics, it's very low. So they are going to pay high taxes to subsidize people like me, and then when it's their turn, the rules are going to be very different.

I worry about Medicare beneficiaries. I've devoted much of my career to the Medicare program because I care about it, and I care about social insurance, but I really worry that the system is antiquated, and it doesn't work for the rest of the country. It's not really fair to the rest of the country.

Having said that, I know in my conversations with Jack and Cori about this, there are lots of really complicated issues about how you make a transition, and I don't pretend to have the answers to those. But I do think this discussion is in part analytic, and this is really good work, but it's also in part about values and I think what's fair to the rest of the country.

So, on that note, over and out. I am done.

[Laughter.]

MR. HACKBARTH: Thank you for the work on this

folks, and we will have our public comment period.

[Pause.]

MR. HACKBARTH: Nobody. We are adjourned. Thank you all.

[Applause.]

[Whereupon, at 11:56 a.m., the meeting was adjourned.]