MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, March 5, 2015
9:40 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHERINE BAICKER, PhD
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
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [9:40 a.m.]

MR. HACKBARTH: Okay. Good morning. Welcome to people in the audience who have come out into the muck to join us. Because of the weather, this is a little bit unusual as a meeting. First of all, we have three Commissioners who are not here because their flights were canceled in anticipation of the snow, so we have a somewhat smaller group.

In addition to that, we've had to make some adjustments to our agenda in order to accommodate things like staff members who have child care issues and difficulty getting here, et cetera. And we have had to delete one item altogether from our agenda for this meeting.

The revised agenda was published on our website yesterday evening about 6 o'clock, and as I say, it's a little bit different order than we first announced. And so if people somehow didn't get the message and the topic that they were expecting to hear is not actually happening when they thought it was going to happen, I apologize for that. But we have got to cope with the weather conditions as best we can.

Because of how our schedule works with the

Congress and how our schedule works with our Commissioners, rescheduling meetings simply is not possible for us. So we need to make the best of the circumstances and get our work done as best we can, whatever the weather.

Anything to add to that, Mark?

[No response.]

MR. HACKBARTH: Okay. So with our revised agenda, we're going to begin with hospital short stay policy issues, which we have now been discussing for, I think, four years at this point, a while, and we are at the point at this meeting when we will be considering some draft recommendations. These are draft recommendations. We will discuss them at this meeting. And then I will discuss them individually with each of the Commissioners between now and the April meeting, and we will bring back a package of final recommendations in April, and at that point we will have our votes on final recommendations.

So, with that preface, Zach, are you leading the way?

MR. GAUMER: Yes, sir. Good morning. Today we are going to continue the Commission's discussion about short hospital stay issues by reviewing the Chairman's draft

recommendations. These recommendations have been developed based on our three previous discussions on this subject. Based on your feedback, we will revise these draft recommendations and return to you in the April meeting, through rain, sleet, or snow. In April, the Commission will vote on recommendations that they are considering.

As you recall, this subject has grown out of both the complexity of the clinical judgment of admission and the payment difference between similar inpatient and outpatient stays. These factors led Medicare recovery audit contractors to focus their audits on the appropriateness of one-day inpatient stays. In response, hospitals began increasing their use of observation status.

While liability is generally lower for beneficiaries served in outpatient observation, its increased use has exposed more beneficiaries to higher financial liability in two particular areas: coverage for SNF services and co-insurance for self-administered drugs. An additional concern is that beneficiaries are occasionally surprised to learn that they are in observation status and also unaware of how this may affect their SNF coverage or their liability for prescription drugs.

Today's presentation will focus on five draft recommendations.

First, we will cover a recommendation, with three subsections, developed to address concerns about the RAC program. Second, we will discuss a recommendation concerning a hospital short-stay payment penalty concept. Third, we will cover three different recommendations that all pertain to beneficiary protections. In the aggregate, we expect that the Chairman's draft recommendations will increase Medicare spending. As a matter of course, we have also identified policy concepts that generate Medicare savings. And we will also discuss these concepts in the context of future policy development.

Before we begin talking about the recommendations themselves, I want to mention two subjects that we have talked about in recent months that are not built into the Chairman's draft recommendations.

The first is the subject of the payment cliff existing between similar inpatient and outpatient stays. In our three previous discussions, the Commission has highlighted the advantages and disadvantages of the various payment policy approaches to try to reduce or eliminate the

cliff. The Commission has noted that there are trade-offs to these approaches because each may replace existing vulnerabilities in the payment system with new vulnerabilities. Approaches that could be considered are: creating one-day stay DRGs within the current IPPS, creating new site neutral payments for similar inpatient and outpatient stays, and creating a new payment system which would lie between the inpatient and outpatient payment systems for short inpatient stays.

In addition, in January, Kathy, you asked us to describe how the inpatient DRG recalibration process works and to consider how recalibration might affect the payment cliff. We are happy to take your questions on this today, but, generally, we just want to tell you that we believe that the recalibration will likely not correct the cliff completely, but may alter it somewhat over time. Also, depending upon the movement of cases between inpatient and outpatient, recalibration could actually shrink or expand the cliff.

The second subject we want to touch on briefly is the new set of rules CMS recently released for the RAC program. We discussed these in January. Some of these

rules overlap with the Commission's ideas about improving the RAC program to some degree. However, because the implementation of CMS' new rules are not an absolute certainty at this time, due to a pending lawsuit, the Commission has decided to proceed with its recommendations.

The Commission has identified three primary concerns about the RAC program.

First, there is concern that the RAC program has significantly increased the administrative burden of hospitals. This has occurred broadly across most hospitals rather than being limited to particular hospitals with abnormal practices. Given that a disproportionate share of hospitals account for many of the short inpatient stays, it appears that at least a portion of the administrative burden may be unnecessary.

Second, there is concern that the RAC program does not sufficiently hold RACs accountable for their auditing determinations. Due to their contingency fee reimbursement structure, RACs have the incentive to deny claims. In addition, recent increases in appeals suggest that RAC denials may not always be accurate.

Third, there is concern that hospitals are unable

to rebill RAC-denied claims as outpatient claims. Currently, RACs can go back three years to audit Medicare claims, and hospitals have one year from the date of service to rebill Medicare for denied inpatient claims. Therefore, when a RAC denies a claim that is three years old, the hospital is not permitted to rebill that denied claim because the claim is beyond the one-year rebilling period.

These three concerns have led to a three-part Chairman's draft recommendation aimed at relieving hospitals of administrative burden, improving RAC accountability, and better aligning RAC audits with the hospital rebilling program. Now, we are going to walk through each of these three pieces separately and discuss the implications of each.

The first of these three concentrates on how to reduce RAC-related administrative burden. By focusing on hospitals with high rates of short inpatient stays, RACs could more accurately identify hospitals with the bulk of these stays and more appropriately place the administrative burden on these same hospitals.

Therefore, the Chairman's draft recommendation reads as follows:

The Secretary should direct Medicare Recovery Audit Contractors to focus reviews of short inpatient stays on hospitals with the highest rates of this type of stay.

In terms of the implications of this recommendation, we expect this policy will increase Medicare program spending because it will result in fewer claim denials and a lower level of recoveries from the current RAC program. We do not expect this policy will adversely affect Medicare beneficiaries with respect of access to care or out-of-pocket spending. This policy will increase RAC scrutiny and administrative burden for hospitals providing a high rate of short inpatient stays, but for the remainder of hospitals this policy will reduce RAC scrutiny and administrative burden.

The second part of the Chairmen's draft recommendation concentrates on making RACs more accountable for their audits. If the RAC contingency fee structure were to include an element of performance-based payment, the program might observe improved audit accuracy and fewer appeals.

Therefore, the Chairman's draft recommendation reads as follows:

The Secretary should modify each RAC's contingency fees to be based, in part, on its claim denial overturn rate.

We expect this recommendation will result in an increase in Medicare program spending because this policy will encourage RACs to take a more cautious approach to auditing and therefore result in fewer denials and a lower level of recoveries. We do not expect this policy will adversely affect beneficiaries. This policy has the potential to reduce administrative burden for hospitals because RACs could become more cautious in denying claims.

The third part of the recommendation aims to synchronize the timing of RAC audits with the Medicare rebilling policy. As I noted earlier, the RAC three-year lookback period and the one-year rebilling period are misaligned, keeping hospitals from being able to rebill many RAC-denied claims. Better aligning the two timelines would enable hospitals to more frequently rebill RAC-denied claims for the appropriate outpatient services on those original claims.

The Chairman's draft recommendation reads as follows:

The Secretary should shorten the RAC lookback period for reviewing short inpatient claims.

We expect this recommendation will increase program spending because it will increase rebilling opportunities and allow hospitals to gain reimbursement for services that were otherwise denied. We do not expect this policy will adversely affect beneficiaries. We expect this policy will benefit hospitals financially by enabling them to rebill more of their denied inpatient claims.

Our evaluation of the RAC program has also led the Commission to consider the potential for a formulaic payment penalty on hospitals with excess levels of short inpatient stays to replace RAC reviews of these stays. Interest in this concept stems from concerns noted earlier, such as hospital administrative burden, the focus of RAC on short inpatient stays, and the subset of hospitals providing many of the short stays. Targeting the audits may alleviate a portion of these concerns, but a formulaic penalty might make the oversight of hospitals more efficient and reduce the administrative burden for all hospitals as well as for CMS.

Therefore, the Chairman's draft recommendation

reads as follows:

The Secretary should evaluate a formulaic penalty on excess short stays to substitute for RAC review of short inpatient stays.

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. Any policy that was implemented out of this evaluation would have a budgetary effect similar to the targeting policy mentioned earlier in the presentation.

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

MS. CAMERON: As Zach mentioned, the Commission has expressed concern about how the recent increase in outpatient observation stays has exposed Medicare beneficiaries to greater financial liability and that this liability could come as a surprise to beneficiaries who were not notified that they were receiving outpatient observation, not inpatient, care.

Specifically, 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 several policy options with regard to revising the SNF three-day prior hospitalization policy, beneficiary notification requirements, and beneficiary financial liability for self-administered drugs which we will discuss today in turn.

First, I'll review the three-day prior inpatient hospitalization requirement for SNF coverage.

A small group of beneficiaries incur high out-of-pocket costs because their three-day hospital stay did not include three full inpatient days, leaving them without SNF coverage. As you may recall, time spent in outpatient care, including outpatient observation, does not count toward the three-day requirement for SNF coverage. Broadening the criteria for SNF coverage would expand SNF eligibility and, thus, the Medicare benefit; however, there has been interest in preserving the SNF benefit as strictly a post-acute care

benefit rather than a long-term care benefit.

In an attempt to find a balance between those two issues, the Chairman's draft recommendation reads:

The Congress should revise the skilled nursing facility eligibility requirement, such that for beneficiaries formally admitted to the hospital as an inpatient, time spent in outpatient observation status counts toward the three-day prior hospitalization threshold.

The Commission anticipates that this policy will increase program spending as several thousand beneficiaries will now qualify for SNF coverage. The overall impact of this policy on spending is dependent on the behavioral response of the beneficiaries and providers. By establishing a lower threshold for Medicare SNF coverage, this policy could encourage providers to extend stays in the hospital in order for their patients to qualify for SNF coverage. The lower threshold could also provide an incentive for nursing facilities to send beneficiaries to the hospital in order to re-qualify them for the SNF benefit.

The Commission anticipates that this policy will have a positive impact on the relatively small group of

beneficiaries who are discharged to SNFs without Medicare SNF coverage. Beneficiaries such as these will see their out-of-pocket expenses for post-acute care liability reduced dramatically.

The Commission also expressed concern that beneficiaries are often unclear about the difference 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 other cost-sharing liability.

Four states now have laws requiring hospitals to inform patients about their status in observation, while several other states are currently considering similar legislation. Last week, the House Ways and Means Committee marked up legislation addressing this exact issue on the federal level. I would be happy to discuss the states' policies or the recent legislation further on question.

In the meantime, the Chairman's draft recommendation to address beneficiary notification issues

reads:

The Congress should require, as a condition of Medicare payment, that all acute-care hospitals notify beneficiaries placed in outpatient observation status for longer than 24 hours of their observation status and that their status may affect their cost sharing for their current hospital stay as well as coverage for skilled nursing facility care.

This policy may have an effect on Medicare spending through changes in beneficiaries' decisions for post-acute care. This policy option may provide beneficiaries with the basic information they would need to plan for their post-acute care needs; however, the spending implications of this are unclear. We expect that hospitals will need to make administrative adjustments to accommodate this change. Hospitals will likely incur an administrative cost to implementing this policy.

Lastly, we'll talk about options related to self-administered drugs and 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 is substantially higher than the cost of providing the drug.

One option to address this concern is to package self-administered drugs in the outpatient payment rate. Based on this, the Chairman's draft recommendation reads:

The Congress should package payment for self-administered drugs during outpatient observation on a budget-neutral basis within the hospital outpatient prospective payment system.

This option would increase the outpatient payment for observation care to reflect coverage of self-administered drugs, while the payment rates for other

outpatient services would decrease slightly to offset it, resulting in no additional Medicare spending.

Overall, this option would also reduce beneficiary liability substantially. Beneficiaries 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 that charge for self-administered drugs would experience a small decrease in revenues. However, this policy may reduce hospital administrative burden associated with cost sharing collections and beneficiary complaints concerning self-administered drugs.

As we have noted throughout the presentation today, we expect some policy options to incur costs to the Medicare program. You'll remember as part of our ongoing conversations other policies have surfaced that would reduce Medicare spending. While we didn't make specific recommendations about these policies today, these are issues that we plan to come back to in future work. These include the ideas of expanding the hospital post-acute care transfer

policy to hospice, recovering $4.5 billion in overpayments to SNFs, and exploring a nursing facility penalty for nursing facilities with excessive rates of preventable hospital admissions.

That concludes our presentation today. For your reference, here is a quick summary of the draft recommendations we've discussed, and with that, I will turn it over to Glenn.

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

Before we start the discussion, let me just make an observation about the offsets. I've always felt that an important part of our self-imposed discipline is that when we make recommendations that would increase Medicare expenditures, that we try to say, here are some ways that might offset those costs.

I do worry, however, that when things are characterized that way, it can sound like, oh, these are offsets that are just strictly financially driven. There's no policy rationale for them. In a way, it weakens the recommendation. And, that's doubly the case if those offset recommendations don't go through our normal process of

policy development, review, draft recommendations, public discussion, and then final votes.

So, what I'm trying to do here is have the best of both worlds. We have identified, not just today, but over the course of our conversations, some areas that we think are worthy of investigation that may produce Medicare savings, that would offset the cost from today's package of draft recommendations. But, they will go through the normal MedPAC policy development process and be considered each on their own merits. We won't do something hasty just to say we have offsets. So, that's how I've elected to handle the offset issue.

In terms of how to organize our discussion today, what I propose we do is break it into three parts and discuss, in turn, first, the RAC reform related recommendations, which are 1-A, B, and C, and go through those and hear whatever comments and suggestions Commissioners have, sort of tie that up. Then move to the notion of financial penalty, Draft Recommendation 2, sort of go through that, hear what everybody has to say, and tie that up. And, then, finally go to the beneficiary protection recommendations, which are Recommendations 3, 4,

and 5.

It seems to me that's a better approach than sort of jumping around from topic to topic in our conversations. It certainly will make it easier for me to sort of follow what's going on and gauge what Commissioners think.

So, that's my approach. We'll begin, though, with an opening round of clarifying questions, strictly defined, and it can go across any of the five recommendations or topics that aren't covered by the draft recommendations that may be in the paper, for example. I ask people to be real disciplined about confining that to clarifying questions, you know, what does this particular statement mean, as opposed to offering broad observations about the policy.

Once we go through round one clarifying questions, then we will proceed to talk about the RAC reform package and so on as I've described.

Okay. Round one clarifying questions, beginning with Dave, and then Jack and Kathy and Jay. We'll go around this way.

DR. NERENZ: Okay, thanks. Great work, as always.

Slide 2, please. On the second bullet, where we talk about profitable, I wonder if you can just remind me,

what assumptions do we make about any cost differences between an outpatient observation and a similar length inpatient admission. You know, clearly, the payments are different. Do we assume no cost difference? Do we assume a little cost difference? I assume this ground has been covered. I've just forgotten.

MR. GAUMER: So, when we're looking at the costs, we're pulling the charges off of claims and calculating the cost based on using the cost-to-charge ratios, is how we did that. So, you know, I think the basic answer is that the costs are calculated for each of the inpatient and outpatient stays separately based upon what's on the claim.

DR. NERENZ: So, I guess my assumption isn't correct. I mean, obviously, you've looked at it. Are there, in fact, significant differences in cost between inpatient and outpatient similar length, say, 24 hours?

MR. GAUMER: Do you want to do --

MS. NEUMAN: So, we've estimated costs for inpatient and outpatient, and it's a little bit tricky on the outpatient side, because as we've talked about, there's allocation issues and so forth to get at the true cost. They look -- that said, there is some -- they look --

there's some similarity, although the outpatient costs do look lower than the inpatient, to some extent. But, again, you really have to caveat it because of all the allocation issues.

DR. MILLER: And also, if I remember -- and there has been a lot of conversation and paper on this -- there were a couple sets of DRGs where we made comparisons across, right, that are in the paper, and there were sort of -- so, I think there's some information on this, I think, you can go back to in the paper. But, another caution might be, I'm not sure we went wall to wall. We took sets of things and looked at them, and I'm not sure we ever made analysis that cut across everything, depending on how extensive your question was.

DR. HOADLEY: My question relates to the set of Slides 7, 8, and 9 on the RAC recommendations. In each case, you say these increase program spending. I assume the amount to which it would increase spending is probably hard to be very precise about. My assumption is that it's pretty small, but my maybe more important assumption is that in each case, it's somewhat variable, depending on how these are all statements in direction focus on hospitals with the

highest rates of stay. If it was -- whatever threshold is going to dictate how much the cost is going to be, is that right?

MR. GAUMER: Yeah, that's right, and so when we were thinking about what they would each cost, it was really in the context of, what are the recoveries that the RAC program is currently generating and how would those recoveries be affected. I think, you know, tying specific numbers to each of them is very problematic, but I think what we can say is that the Part A here would potentially come in lower and cost money as a result, yet lower than current recoveries and cost money or increase spending. The rebilling, essentially, if you did A and B together, would make the cost a little bit larger because you've got more money going out the door to the hospitals for the rebilling for claims that they hadn't previously been paid for. And, then, the costs related to -- or the spending increase related to C is somewhat negligible. We don't think that it's going to dramatically increase spending, but it's going to change behavior of auditing slightly as they become more cautious in their auditing. Thank you.

DR. MILLER: Glenn asked me to remind you guys and

the public of a couple things. When we come back in April, we'll try and have our usual buckets thing where we have ranges of estimates that we've tried to work through with CBO. That's always contingent on their ability to work through their other workload.

The other thing that's particularly -- and I think you will get this instantaneously, there may be some others that this might be news to -- this is particularly complicated because this isn't a legislative action. It's an administrative action. So, the whole CBO process is very different and we may not end up with buckets here. And, I think it's further complicated by the fact that there are some regs out there which implicitly shift the baseline and how people are counting and thinking of that, makes it even more complicated than the usual set of problems.

But, for those things that are administrative and not these things that you just asked about, hopefully, we'll come back with the buckets.

MS. BUTO: So, I think Mark just answered my question. All of this can be done administratively if CMS were to say, you know, we totally agree with you, we'd like to make these changes.

And the second question I had was what the cycle is for contracts with the RACs. In other words, how quickly could CMS make any of these changes? Do we know?

MR. GAUMER: Okay. So, CMS has this list of 18 changes to the program that are out there, and what we've heard is that these, they want to put into the next contracts, which are going to begin very shortly. I think they started a new -- they've been trying to sign a new contract for DME and hospice and some other things which has been held up by a lawsuit about getting the terms of the contract ironed out. So, that's currently kind of being worked out.

In terms of when the hospital-related stuff is going to be contracted, that's kind of unclear, but CMS has said shortly. These new contracts need to be renewed quite soon. And, when they come online, they want to have these 18 new rules embedded in those contracts. They've also indicated that they have some leeway with implementing these 18 new rules, kind of on an ongoing basis, in the gap period that exists between March 31, when the moratorium on RACs is lifted, and until the new contracts are signed.

And, in terms of how these recommendations and how

quickly those might be implemented, I think that they would kind of follow the same timeline. You know, it depends upon when the new contracts get signed and CMS might have the ability to put some of these ideas into shape, in part, before the contract is officially done.

DR. MILLER: I'm sure that this was clear in your mind, but just to be clear to other people, you're referring to the RAC recommendations as administrative actions. There are other -- for everybody out there -- there are other recommendations that will be Congressional in nature. We'll note that as we go through it.

DR. CROSSON: Yeah. My question is on the beneficiary notification recommendation. You mentioned that there were four States that have addressed this issue and there's a markup in Congress. In any of those cases, does it specify when in the stay that notification should take place?

I'll just say, because -- and I don't have a fixed opinion, but it would seem to me that if you did it right at the beginning, it would be somewhat untoward, you know. A gentleman comes in with chest pain and is worried about a heart attack, and at the same time you say, well, in fact,

if you require SNF and we don't put you in the hospital, then you're going to have to pay -- I mean, I can't imagine being the person having to do that. It also, potentially, would put the physician in a funny place with the patient, who might say, why did you put me here instead of in the hospital? On the other hand, I think some beneficiaries notified after could say, "Well, how come I didn't know that beforehand? Now, it's too late."

So, where has the thinking been on that issue?

MS. CAMERON: So, the four States that currently have these similar laws passed typically benchmark right around the 24-hour mark. One State, for example, says exceeding 23 hours. Another few say within 24. So, there is kind of some thinking that right around the 24-hour mark is the time that they've chosen.

In terms of the draft legislation that's going through the House of Representatives right now, that includes a 24-hour mark, but gives another 12 hours for the oral and written notification. So, really, within 36 hours.

One State in particular specifically says that if the patient is admitted, this notification does not need to be given, and they're very explicit about that. So, if the

24-hour mark comes and goes and the beneficiary is still in outpatient observation and then gets admitted prior to having this notification given, it's null and void. The legislation specifically says, you do not need to give it.

The other States don't explicitly address this, and it's unclear how it's being interpreted. That is being interpreted on the ground right now.

DR. CROSSON: Thank you.

MR. HACKBARTH: Jay, you carefully crafted this as a question about State legislation and what Ways and Means is doing. Thank you for doing that.

I hope you will raise this issue again when we talk about the draft recommendations, because having talked to all the Commissioners, I know there's some different ways of thinking about the timing and nature of the beneficiary notice. So, this is an important issue for us to discuss further.

Jon.

DR. CHRISTIANSON: So, I kind of had the same question as Jay, except there were two other sort of continuing thoughts on that. Is there anything we've learned from those four States that have actually informed

the Chairman's recommendation here? So, that's my first question.

My second question is, has anybody done any follow-up to figure out whether, in fact, this has reduced beneficiary confusion and added to better decision making, or whether, as hospitals, some hospitals suggest, is just something else that they have to do?

MS. CAMERON: So, the four States that have implemented this, we've spoken with one hospital -- a representative group from one of the States, and they have said that what made this a less arduous task for them was having the State actually put together a notification draft for the hospitals that provided the minimal elements required by the law. So, hospitals, essentially, were provided with a template, and it's our understanding that this particular State did work with other States on kind of best practices on how to roll this out and didn't seem to convey that this was a large burden on the hospitals in the end.

One of the reasons they cited for that was, one, they had this template that provided the minimal notification. It was a simple letter. The first paragraph

explained this notification notifies you that you are in observation status.

The second was -- paragraph, and really the second sentence said, your placement in observation status may have implications on your cost sharing for this stay and subsequent care, and the degree to that care specified varies by State law.

And then the third sentence said, we encourage you to contact your insurance provide, whether it be Medicare, Medicaid, or private insurer, and all the States have kind of a very similar target.

So, I think that's something that we did learn, that there is kind of a template that helped hospitals give this notification.

The second piece, I should say, is we learned that, typically, at least in one State, this is not something, and the hospital representatives felt strongly, this is not something that a clinician should be providing to the patient. Instead, they notified us that it was either a social worker or other employee of the like, including an administration registrar, who actually provides this information.

DR. CROSSON: So, this is very helpful for me in understanding how this might work. So, two things.

One is, is there any evidence, or has anybody looked at this closely enough to say that this has changed hospital behavior in terms of the way they use observation status, or that beneficiaries have changed their behavior as a result of having this information?

MS. CAMERON: Not that we know of to date. In our conversations with this hospital group, they did not indicate one way or the other, but that is something, if you're interested, we could certainly look into.

DR. MILLER: These are relatively recent, though, right?

MS. CAMERON: That's right. So, that's the -- right. So, these laws mostly passed in the latter half of 2013 or 2014, so they are fairly new, kind of hitting the ground running.

DR. MILLER: These are relatively recent, though, right?

MS. CAMERON: That's right. Right.

These laws mostly passed in the latter half of 2013 or 2014, so they are fairly new, kind of hitting the

ground running.

MR. GAUMER: I just want to add one more thing, just another thought. Stephanie has hit on all the most important stuff.

The one thing I would underscore here is that the group that we spoke with indicated that this part that Stephanie described about requiring the hospital to say that the insurer should be contacted if you want more information about your coverage was among the most important pieces that this group was advocating be included in the legislation to help assist to the hospital or the clinician, with not having to understand all of the dynamics of coverage in that state that exist. So I just want to underscore that point.

MR. HACKBARTH: Yes. I think this discussion just highlights the complexity of the situation. Based on what Stephanie reported, states have quite appropriately taken into account how do we minimize the burden imposed by this on hospitals and not put hospitals or physicians in the position that Jay described of saying to a vulnerable patient, "Let's talk about your insurance coverage and what you may not be covered for," and those are all important things.

On the other hand, if I'm a beneficiary and I get this letter and it says, "You may want to call your insurer and talk about your coverage," yes, I'm not sure that it's really done much in terms of beneficiary education.

It maybe says there's something that I need to look into, but realistically, for patients under duress and given the nature of these issues, I think maybe, at most, we've made a very tiny gain and beneficiary education.

Having said all that, I don't know what a really perfect solution is to this very complicated challenge.

Alice, clarifying question?

DR. COOMBS: So Slice 9, one of the questions that came to my mind was that it was clear that there are a number of providers going through the appeal process, and other ones that went through the appeals process, there was a 50 percent success rate in terms of affirmation.

Is the three-year RAC look-back -- eliminating that was one issue, but the other issue is one-year claim rebilling cycle. Is that enough? Because some of the appeals backlog -- and I don't know. With the RAC reform, that's going to change, but is that enough to be able to get the rebilling, go through the appeals process and get the

rebilling? What is the synchrony in terms of being able to do what's necessary for hospitals to go through the appeals process, get an affirmation, and then rebill?

DR. MILLER: Can I pick this up?

We talked about this internally, because there are essentially two moving parts: how long can you rebill, how much of a look-back do you give. At least a couple of things that we would suggest you guys focus on is you probably don't want a long enough period that a hospital can move entirely through the appeals process because then you set up an incentive for them to appeal everything and then rebill.

You probably want some window for them to say, "Okay. I got this denied. Am I going to fight it, or am I going to just step out and rebill?" So you want your -- I'm going to get this all wrong. You want your look-back period to be shorter than your rebilling period.

We are implicitly assuming there is a one-year rebilling period because that's what's out there. I suppose you could take that on too, but now you got two moving parts you got to keep an eye on, and the only point I am trying to make is you want your look-back to be shorter than your

rebilling period in order to create this incentive, that you want the hospital to say, "No. This is a good claim. I'm going to fight it," or, "Okay. I'm going to walk away. I'm going to go and rebill for the outpatient."

So that would be the principle I'd ask you to keep in your mind. If you want to open the rebilling, that is a separate piece, and I want you to know in the back of our minds, we have been sort of saying, "Well, it's a year," so --

DR. COOMBS: That's good, Mark.

So we're making an assumption that that whole appeals process moves quite expeditiously.

DR. MILLER: Well, there are --

MR. HACKBARTH: That would be a heroic assumption.

DR. MILLER: Yes. I don't know that we made that assumption. I'm trying to set up principles of rebilling periods versus look-back periods, try and keep those kinds of incentives in mind. I think that's more what I'm saying.

And I think you might want enough -- and I am now making this up. Actually, I've been -- through the whole thing, I've been making it up. In the look-back period, you might want some amount of time for some step in the appeals

process to occur but not all of it, because then you are just going to have the backlog and the rebilling.

DR. COOMBS: I guess maybe what might be helpful is to know the one-year -- the claim rebilling process incorporates some piece of that appeals process that's separate from that, or how does that work?

DR. MILLER: Yes. Do you want to go through and pick it up?

MR. GAUMER: Yes.

There are five different levels of appeal. You probably saw the footnote in the paper that's about that long. There are five levels of appeal. We have not heard of delays in the process at the first two levels. The way I understand it, these are almost automated appeal processes, and it's not until you get to the ALJ level. Is it the fourth level of appeal?

DR. MILLER: Third.

MR. GAUMER: Third level of appeal, where you start having an ALJ, a judge, sitting there looking at the case and considering each and individual case. That is where the bulk of the delay is coming.

Among these 18 new rules that CMS has put out is

one that goes to this topic which indicates that they'd like to move the look-back window to 6 months. We had to consider what that does to the appeals process, and it's our understanding that basically that gives the hospital as much as a chance to go through one or two levels of appeal and probably not get to the third level of appeal. That is up to you to decide whether or not that's appropriate or not, but we think they could get to at least maybe one or two levels of appeal. Yes.

MR. HACKBARTH: Bill.

MR. GRADISON: Just circling back to this question of state notification, my understanding is that the state notification applies to all cases, not just Medicare. Is that correct?

MS. CAMERON: That is our understanding as well in the states that have implemented this. Yes.

MR. GRADISON: I bring it up because if we have a standard, I could see the complication of having to have one notification, "If you are covered by Medicare, it's this," another part or a different page if you are not.

The only reason I mention that is there might in a case like this want to be something that would require the

federal -- the federal required notification would perhaps be waived if there was a satisfactory -- a notification satisfactory to CMS that was already being required for everybody else. I just want to make that point.

MR. ARMSTRONG: Thanks, Glenn.

Alice's question took us most of the way through the question I had. First, I really endorsed this idea that there are two moving parts. Let's not mess with the appeals process at this point. Let's just look at this look-back period.

But my question specifically was just going to be why aren't we more specific in our recommendation about what that look-back period is. In your elaboration, we are presuming a bunch of things, that it's shorter than one year and that kind of thing. Why don't we just say it's less than one year or something more specific?

DR. MILLER: I'll start this one, and by the way, in our lottery, all these questions came up.

[Laughter.]

DR. MILLER: We're going to have to settle out in cash on this, not that we do a lot of that with you guys.

[Laughter.]

DR. MILLER: I think this one falls to me because we're at -- you could say six months. We were trying to really, consistent with the Commissioners' statements -- CMS has entered the field here, and they have said, "There are some things we want to do," and then there are some things holding that up, as you know and you've discussed. And then there were statements made by Commissioners, "Well, we should say, anyway, what we think should go on."

So what we're trying to do with these recommendations is make clear at a principled level what we want to happen. Underneath it in the text, we can talk about ways for it to happen, but leave some flexibility there for the Secretary to act.

If you guys don't want to do that, then obviously, we can be more rigorous, but we start with the notion of principle and then text to talk about ways to do it.

And I'll just say this for myself. I don't feel, particularly, when I think about the CMS folks and trying to implement these ideas, that I have thought of every possible angle and that I could end up having thought all of it through. For myself in drafting these things, I am trying to leave some leeway there, but if you want more precision,

it's your call.

MR. ARMSTRONG: Thank you.

One other brief question. When we talked about Medicare program spending, does that include the payments that the Medicare program makes to the RACs?

MR. GAUMER: Not necessarily, no. We are talking about payments to providers.

MR. ARMSTRONG: Okay. In fact, we talk about incremental program spending, but we are actually shifting spending from RACs to the providers. I don't know that it is a one-for-one, but is that the right way of thinking about that?

DR. MILLER: Meaning that the dollar that might have been recovered stays with the hospital.

MR. ARMSTRONG: Correct.

I presume you lower the denial rate. You lower the contingent payment to RACs. You increase Medicare spending to the providers, but some of that is really actually shifting our spending.

MR. HACKBARTH: Right. Because the RACs are paid a share of denied admission. If the admission is permitted, only the portion that wouldn't have gone to the RAC is the

additional Medicare spending.

MR. GAUMER: That's correct.

MR. HACKBARTH: Okay. I think that we have actually sort of crossed the line between Rounds 1 and 2. Again, while focusing on the RAC reform-related recommendations, let's officially announce we are in Round 2, and here, I am really interested when people talk for you to say either "I support the recommendations as framed," if not, why not, and how you would like to see them modified so that you could support them.

Do you still want to go, or do you want to think some more, Rita?

DR. REDBERG: I had a clarifying question.

MR. HACKBARTH: Okay. You will be the last. Go ahead.

DR. REDBERG: Sorry.

MR. HACKBARTH: That's all right.

DR. REDBERG: But it relates to page 13, the footnote on the levels of appeal. I am not sure what the automation part was. The first two levels, the MAC and the QIC have a level of automation, what does that mean?

MR. GAUMER: Yes. I think the way that works, the

claim gets kicked back to the MAC, the administrator who is processing the claims, and there is more of a computer automated process that checks a series of edits to make sure that the claim has the appropriate information on it and all the fields of the claim are filled out, and if it's not one of those types of things, if it's not inappropriate for that reason, then it goes back to the hospital, and the hospital has a chance to appeal to the next level.

I can't really speak to the distinction between what occurs at the MAC and the QIC level, the second level of appeal, but that's the sense that I have. They are automated. There is not a human being looking at a piece of paper with the medical record on it.

DR. REDBERG: The first time a human being looks at it, is that the third level with the ALJ?

MR. GAUMER: That is my understanding.

Do you guys agree with that?

DR. REDBERG: Can I see it?

And are we going to have a Round 3?

MR. HACKBARTH: No.

DR. REDBERG: Okay. I have two questions then.

MR. HACKBARTH: Okay.

DR. REDBERG: It relates to the concerns.

I think the recommendations are reasonable, but my concern, as I think we have discussed, is I think the ALJ -- it is not a medical person making a ruling, and some of the overturns I have seen in general are not really medically reasonable. To have that as a criteria as the overturn is probably as good as we are going to do, but I just want to say that I don't think the ALJ system is a very good system for determining medical necessity.

Then my Round 3 sort of comment is just in the bigger picture and especially because a lot of these short stays are cardiac-related, so chest pain. I think a lot of it, the reason there are so many short stays in the cardiac, is because complaints that really should be seen in a primary care office are then sent to the emergency room for a lot of different reasons, but some of them being that it is hard to reach your doctor. When you reach the doctor, you might have a covering doctor. In the script, as soon as someone hears chest pain, especially if they don't know you, it's to go to the emergency room, and then we have a lot of people that shouldn't be seen in the emergency room ending up in the emergency room. Then a lot of them get held there

for a lot of testing. Ninety percent of those chest pains don't even have cardiac disease, so sort of in our bigger picture, rebalancing. Maybe ACOs will address some of this, but having more incentives to have a true primary care physician access an evaluation, I think would really eliminate a lot of these short-stay units, the observation stays that really should have been seen in an outpatient office.

MR. HACKBARTH: Rita, on the draft recommendations related to RAC reform, can you support them as-is? If not, what would you like to see change?

DR. REDBERG: Sorry if I wasn't -- but I could support the ones that you have there, now that I've said everything else. Thank you.

MR. HACKBARTH: Thank you, Rita.

On this round, this is going to be our last round. Not everybody needs to speak, but I will interpret silence as assent. So if you have reservations, please get in the queue.

We will come down this way with Cori, then Kate.

MS. UCCELLO: I am supportive of these recommendations, but I just have a quick question regarding

risk adjustment.

It matters more, I think, for the second recommendation on how thresholds are set and how risk adjustment is incorporated into that, but I'm also just wondering whether if we're looking at targeting, whether risk adjustment also needs to be incorporated into that part of it.

My understanding is that CMS, what they are trying to do is look more at providers with low denial rates and having lower review of those, and that doesn't seem to need a risk adjustment kind of component to it, but I am just wondering if the targeting would still need something like that.

MR. GAUMER: I think that there is a broad stroke here for recommendation A with things like that in mind. This would be something that the Secretary could decide to do, but risk adjustment could be necessary for a targeting approach.

If you are just looking at the number of short stays, you are going to want to account for which types of short stays or which DRGs you're taking into consideration. Those are all questions, I think, that the Secretary would

have to consider in designing a targeting policy, specifically.

MS. UCCELLO: Okay. And to be clear, I don't think that belongs in a recommendation itself, but just as I'm thinking through this, it sounds pretty straightforward. But the more you think about it, the more complicated it gets. Even this, I think can be fairly complicated.

DR. MILLER: We can make sure that it gets into the text.

DR. BAICKER: I am supportive of the recommendations, and I just wanted to briefly follow up on Scott's point that I think differently about things that increase spending without changing service delivery versus things that increase spending by changing service delivery, and so I think it's important to think through, which we allude to in the text -- and this doesn't affect the recommendations -- how this affects the incentives for providers to change the actual length of stay or what kind of beds people are in, and that has different implications for how effectively we are allocating these health care resources, then shifting -- paying more for a set of services that were delivered, anyway, and we're differently

evaluating whether it was appropriate or not.

DR. COOMBS: I support the recommendations, and with B specifically -- the interface of B and C, I think may make a difference with the behavior of the RAC in terms of the whole appeals process. I'm just more concerned about the appeals process and the rebilling for hospitals and how that actually works, but I think B will help with C in terms of the whole process of being able to rebill.

DR. CHRISTIANSON: I also support the recommendations. I think -- as a package. I think I like the idea in A that we are trying to make allowances for hospitals that don't have a history of this, and also maybe create an incentive for hospitals to be in that group and not be audited.

I like the accountability aspect of Part B, holding RACs more accountable for their actions.

I like C because it addresses something we've talked a lot about, which is the fairness issue. But I really think -- and what Alice just said illustrates it. I really think I like this as a package, and I think there's going to be a real temptation to sort of pick one or pick the other, and I think this is a nice set of reforms in this

whole process viewed as a package. And I like the generality involved, again, building off of what Cori was saying, not getting real specific, but obviously there are a lot of specific issues that will have to be addressed, so having it at a general level makes a lot of sense to me as well.

DR. NAYLOR: I also like the recommendations and like the notion of them as a package. The one recommendation I would have is in -- and, actually, it's probably antecedent to all of these -- is to -- the report talks about at one part, page 16, 17, the two-midnight rule and later talks about how MedPAC defines short stays. And I think all of these should be framed in the context of what exists and what might happen and implications for that. So just a couple sentences in the description.

DR. CROSSON: Yeah, I also support the recommendations. With respect to Recommendation 1C, I had thoughts I think similar to Scott, which is when I looked at it I said, well, why doesn't it say six months? I mean, when you think about what we're actually talking about, if it was too short, it would make no sense at all. There would be no lookback practically. And if it's more than a

year, then it kind of frustrates the whole point of what we're doing.

So, you know, if you're just sort of eyeballing it, it's going to be within a range of something like four months, eight months, something like that.

I'm fine with not specifying that for the reasons that Mark described. I just think that in the text -- and I think it is clear in the text, but in the text it ought to say something like, you know, it needs to be in this range or something.

MR. KUHN: I too think the recommendations make sense. I really like 1B. In the area of error rates, there needs to be more accountability that works.

On 1C, however, just a couple observations, and this too might be able to be handled in the text and not necessarily in the recommendation. But, you know, it has been talked about, the rebilling and lookback period and the incentives to appeal. But we need to understand that when hospitals or anybody makes the decision to appeal, it is expensive. It takes staff time. It's costly through the process. So it's not just something, let's appeal everything. They really have to make a concerted effort

here to make a determination because some of these appeals will cost over $1,000 or something like that. So there is a cost associated with the appeal process, so you don't want to appeal everything. So I think maybe in the text we can align -- or set out what those incentives look like a little bit.

And then I think in the -- you know, how we also think about the lookback process, so we talked about the first two levels of appeal, which were pretty automated. But when it gets to the third level, when it gets to the ALJs, my understanding that until about six months ago the productivity of an ALJ was four cases a day. I understand productivity now is up to six cases a day. This is the neck of the hourglass, and this is where the process really slows down.

And so I just want to make sure we don't put together a lookback process that isn't fair to all parties involved here. So I think the flexibility that you've kind of built in here makes a little bit -- makes sense as part of that.

And then also I just want to make sure that we -- you know, Zach talked earlier about the end of December when

CMS made these 18 recommendations. I think one of the recommendations was to change the lookback process from three-year to one-year, but how does that work then in terms of the rebilling process if it's a truncated process? Just make sure that that all works as well.

MS. BUTO: I can support the recommendations. I like the idea of at least for 1C saying something about even though we may not want to give specific time periods, the RAC lookback period being aligned or shorter than the amount of time allowed for rebilling, something along those lines, so that it's clear that we don't just mean shorter than three but actually we mean short enough that the hospital can rebill. So some clarification there.

DR. HOADLEY: I don't have much to add. I support the recommendations. I think a number of these things, the text is a good place to clarify a number of things we've raised, including the notion of sort of how this relates to the CMS 18-point program, or whatever they've got, to make the changes.

MR. HACKBARTH: Okay. So those are the RAC reform-related recommendations. Let's now turn to draft recommendation 2 on the formulaic penalty, and we're open

for comments on that.

DR. CROSSON: All right. So, you know --

MR. HACKBARTH: And the same rules. If you support or not; if not, what might be changed to win your support.

DR. CROSSON: All right. So I support the recommendation. I think it's a reasonable way of taking a look at it. You know, to reiterate -- and I think it has come up in the last few minutes -- it just seemed to me when we first started looking at this that this whole RAC review process had grown like Topsy with, you know, five levels of review, with a backlog of 800,000 cases at the administrative law judge level. And I wondered whether or not there might not be a simpler way of creating a counterincentive for hospitals rather than create this rather cumbersome and expensive process.

It may turn out that there isn't and that this needs to continue the way it is. But it seems to me reasonable to take a look at it for the same reason that we said just a few minutes ago, we want to support focused review. If focused review is the right direction, and I do believe it brings complications, and I think some of those

are raised in the text, issues like how to establish the threshold for what would, you know, count is the same question, I think. Nevertheless -- and I always hesitate to think, if a little is good, then more must be better. But if we're moving in the direction of focused review, but we're leaving in place a rather expensive and cumbersome process, why not at least take a look at the question of whether there's a simpler way to do this. And so I would support that recommendation.

MS. BUTO: Are we in clarifying questions or all questions?

MR. HACKBARTH: This is Round 2 now. We're beyond the clarifying. So you can ask a question. Feel free to do so. But at the end I want to know where you stand on the draft --

MS. BUTO: Okay. I can live with this recommendation because it's an assessment of the formula-driven approach. I have a real issue with formula-driven approaches that I think I've articulated before, but in particular this one, which to my mind, particularly if it's accompanied by no RAC review or no medical necessity review -- and I don't know if that's the case -- to me would

undercut one of the kind of fundamentals of Medicare, which is that medical necessity should drive whether or not something is covered. If we go to a formula -- and, again, the assessment might unveil the data, but I think you'd have to have pretty good data as to where to set the threshold if you're going to apply a penalty to hospitals, because fundamentally you're going to reduce their ability to serve patients even appropriately. So I have some questions about that.

So I am comfortable with this recommendation, but I do have some reservations about undercutting basic medical necessity review, which I think of -- whether the RACs are perfect contractors in this regard is a real question, and I think we would improve it. But I do feel like there needs to be some sort of oversight beyond a formula.

MR. GRADISON: I can support this, but I'm troubled by the notion that in doing so we say, okay, we're finished with this issue, somebody else is going to look into it, because I think it's very important for the reasons that Kathy has mentioned. So I'll support it, and I appreciate we have enough of a workload in the future that this may not pop right back to the top of the list. But if

you keep a list on the side of things that we might want to take another look at in more detail than perhaps we were able to in the context of all that is before us today, I would put that on that short list. So I'll support it, but [off microphone] I'd just offer a suggestion.

DR. HOADLEY: Yeah, I have some of the same positions as Kathy and Bill talked about. I think this makes sense to go ahead and say we should take a look at this. I'm not sure if I think this works, and being not sure is a good reason to look at it further. Whether we do it or whether we ask the Secretary to do it, you know, are two ways to get there.

I do think sort of as we present this in the chapter, we should be sort of clear on how this relates to the first set of recommendations because, you know, if people sort of read them quickly, oh, you want this and this and this, well, you want this; and then at the same time, you know, we should make sure that nuance gets picked up, and certainly in the chapter it'll come across. It's as you get to the shorter summaries where that gets a little awkward.

MR. HACKBARTH: So Kathy I think raised this

issue, and I actually think that there may be some merit in the idea. But an important design issue is whether this is a substitute for or a complement to administrative review. And I don't know the answer to that, but I think that is something that we could well flag in the text as -- make it clear that that's an open question as opposed to a resolved question.

DR. HOADLEY: Yeah, because I think the wording in the chapter actually used the word "replaced," and it was not yet the text of the recommendation.

MR. HACKBARTH: Right.

DR. HOADLEY: And I think this one, well, it still has the word "replace" in the second sentence here under the rationale.

MR. HACKBARTH: And I don't want to put words in your mouth, Jay, but I think part of the appeal to you initially was to potentially replace administrative review with a system that is more targeted and less cumbersome. Is that correct?

DR. CROSSON: Yeah, I think that's fair. I mean, as I said a few minutes ago, we've already moved down that path with the previous recommendation, that we're going to

not do this for all hospitals, we're going to focus it on certain hospitals. Whether or not, you know, the right solution is to totally replace it and eliminate any process at all of looking at suitability, I think that's something that could come out of an analysis.

Let me just make one other point, particularly since I think we're moving toward support here. One of the attractions I think early for me was just simply saying, well, if we've done this for hospital readmissions and that has been effective, you know, can't we do that for this as well? And, you know, I have to say I've thought about it some more, and one of the things I realized is that the hospital readmission process that we have now with the penalties in place, escalating penalties now, has an additional benefit. It probably drives improvements in quality. I suspect it does drive improvements in quality.

To be honest, I'm not certain that this would do the same thing. I don't know that it would make a lot of difference one way or the other around quality. So it isn't exactly the same, but I do think still that it would be -- if it would work with the modification suggested, it would be an awful lot simpler than this program. And so I

continue to support the idea of taking a look at it.

MR. HACKBARTH: Okay. We need to keep moving along here. Rita, did you have any comment on this one?

DR. REDBERG: Very brief. I could support this recommendation, although I do share Kathy's concerns about the formulaic nature and whether it is consistent with the medical necessity mission of Medicare. And I think there's probably -- there will be more detail in the text about what an excess short stay is.

MS. UCCELLO: I support this recommendation because it is an evaluation recommendation. But I also want to support the absence of a recommendation on a change in payment policy, that we're not including that, and I think that makes sense, because at this point it's just not clear that such a policy would be an improvement.

DR. NERENZ: I certainly support this, and the word "evaluate" I think is the key word. It puts attention on it, but it doesn't implement.

Just Bill and Cori's thought about risk adjustment, and this may find its place in the text somewhere, I think that's going to be important for this in the same way it is for almost any formulaic penalty or

reward system, that you'd want to have apples-to-apples comparisons, level playing field, whatever phrasing we want. The risk or case mix adjustment will probably focus most immediately on clinical factors, you know, whether you have more or less of your share of the chest pain type patients, that kind of thing.

The question I wanted to ask, though, is whether there are any environmental characteristics, community characteristics, things like that, that for some reason may make it harder for a given hospital to have observation stays as opposed to inpatient. Now, there may not be any. I don't know. This is really a question to clinicians or to our administrators in the room, because I just want to put on the table that there may be a domain of adjustment that's not just pure patient characteristics but it's the health care environment characteristics. Unfortunately, I can't give you an example, but I'm putting it out as a question.

DR. COOMBS: I like the idea of looking at formulaic processes. I don't think that I support the piece about the total replacement of the RAC. So the thing that I support most is that it says "evaluate," and the "evaluate" is, I think, where I would support looking at this.

The greatest concern I have is looking at pockets where there are short stays that are necessary short stays, and they're necessary short stays because they prevent worse processes for patients. So I'm sure on the list that we had in the chapter, there's certain entities where you can actually manage someone who is a mild DKA, get them out of the hospital in an expeditious fashion. It's not quite observation status, but, you know, there are bunch of diagnoses that I can -- I'm sitting here thinking about recently of people who we would consider short stays, not necessarily observation stays. And I'd hate for a hospital that does a very good job and is very efficient at those short stays and doing what we say, the quality -- meeting the quality benchmarks, and for those hospitals to be penalized. Recently there was an oncologist who actually manages sepsis very well as an outpatient in chemotherapy patients, but it requires a lot of input. And the same thing might be true for someone with a short stay in a hospital who's a sepsis, who gets out and you say, well, could that have been observation? It's possible.

But I would like to consider some of those diagnoses, and I'm not sure what the distribution of those

diagnoses are, the DRGs are across the different academic versus DSH hospitals versus for-profit/nonprofit status. So I don't have a good picture of what that looks like. I could say I support the evaluation because I think it's important for us to look at what the variance looks like in terms of variations in it. But those are my thoughts.

DR. CHRISTIANSON: I support the recommendation with also Bill's suggestion. I think we don't know where this will end up on the to-do list for the Secretary, obviously, but maybe some additional work on our part if we have the staff ability to do so might provide an additional nudge. And so I think it would be useful to continue to as a staff try to work on this issue if we can.

DR. MILLER: And if I could just say one quick thing about that, because it has come up twice. Generally, my view of this is when we ask the Secretary to look at things like this, we also look at them, because, you know, after all, we're those kind of people, too.

[Laughter.]

DR. MILLER: In a good way. Was that take any other way?

But there is also -- you know, there's lots of

priorities, and you guys raise lots of things to look at. So I never intended to move this off the list, but, you know, Bill's point of which list it's on I think is the question. So I intended to pursue it.

MR. HACKBARTH: Kathy, you wanted to react to something you heard?

MS. BUTO: Yeah, partly something that Jon said, but I think others have mentioned it, too. It occurs to me that -- and I know we don't want to put this in the recommendation because it's an assessment. But if CMS were to adopt this, if this were to pass -- I think it requires legislation -- then CMS may want to drop the two-midnight rule because I think the two-midnight rule complicates this unless you count observation days in coming up with the set of hospitals that are going to be targeted for these reductions.

So I guess my only suggestion is that in the text we at least address the fact that observation days under the two-midnight rule sort of have to be taken into consideration in this assessment in order to figure out what the impact would be, because, you know, the current policy drives hospitals to use fewer inpatient days and use more

observation days. If they then get targeted, that sort of sends the opposite signal. So I'd just say we ought to acknowledge that it's an issue.

MR. ARMSTRONG: So, I just briefly want to acknowledge I understand the concerns that the Commissioners have expressed, and I do endorse this recommendation, particularly knowing there's a lot of questions still to resolve and this is proposing an evaluation.

I would just add, though, that I'm far less concerned about a formulaic approach to identifying penalties and, frankly, believe the vast majority of the payment policies that we recommend are formulaic and that -- so, I just want to be clear. I'm less concerned about that idea and, frankly, think that's largely what we do.

DR. NAYLOR: No, I support the recommendation and suggest that maybe we consider language evaluating a formulaic penalty on excess short stays to either complement or substitute for RAC review, because that's what evaluations do. They come -- and, I think the text really provides a really excellent balanced view on what might happen as a result of the evaluations.

MR. HACKBARTH: Okay. So, we're now ready to move

on to our third group, the beneficiary protection related recommendations, Number 3 through 5. Who would like to begin on that? Mary.

DR. NAYLOR: So, I support this recommendation --

MR. HACKBARTH: We're going to talk about them all as a group, 3, 4, and 5, so --

DR. NAYLOR: Oh, okay. All right. Well, let me start, I support the recommendations, but would encourage in the text the following. On the expanding the three-day hospital stay, that we acknowledged the rationale for keeping skilled nursing as opposed to acute service because of the challenge -- potential challenge around, for example, nursing home churning. I would say that, alternatively, what we will want to say, in the future, we might want to look at this in different ways. It may be a way to avoid hospitalization unnecessarily for people, ACOs that would want to move patients into SNFs.

On the beneficiary notification, I think that that is essential. I would insert the word "require timely" and consider, also, in the text how important the consumer or public education should be around these evolving changes as an adjunct. So, I really think it's very stressful to

beneficiaries to think about notification within 24 hours or 36 hours about these. So, I would really think that we could couple public education with timely notification of patients who are affected by it.

And, that's it.

MR. HACKBARTH: So, on the issue of beneficiary notification, let me just float an idea without endorsement that I heard from one of the Commissioners in my phone conversation. I invite people to react to it, as well. And, I think this approach was the result of a concern that just adding a broad notice, even one like some States are requiring, really doesn't advance the ball of beneficiary education very far. Yeah, it's crafted in a way that it's not very burdensome for hospitals. But, if the objective here is to educate beneficiaries, call your insurance company, it's helpful, but it really doesn't take us far.

So, the idea that was suggested by one Commissioner was, well, the real critical moment is when a hospital is about to discharge a patient to a SNF, and that's the critical opportunity to get an engaged beneficiary and say, you may not be covered for your SNF care because your time here in the hospital was not

inpatient care, it was observation care, and have the conversation at that moment in a very focused way with the beneficiaries who are directly affected as opposed to one more piece of paper on that clipboard that everybody signs as they pass through the hospital.

So, I'd ask people to react to that idea, as well. Mary.

DR. NAYLOR: So, I think that the public education outside of the stressful environment is really a desired opportunity. Hitting people at the time of discharge is really challenging, because they have to think about what their alternatives are. And, if they cannot and do not have the family support, et cetera, then you could create a whole different scenario.

So, I would say that "timely" should mean as early as possible for the individual in the hospitalization so that they can really anticipate and plan for their next site of care. But, I don't think it's adequate and needs to be coupled with public education.

MR. HACKBARTH: [Off microphone.] Let's go this way with Scott, and again, silence is okay, but it will be interpreted as assent, and we're talking about all three of

the beneficiary protection recommendations, 3, 4, and 5.

MR. ARMSTRONG: [Off microphone.] -- assent.

MR. HACKBARTH: Okay. Alice.

DR. COOMBS: I think I had a conversation with you on the phone regarding the beneficiary notification. I support the recommendation, and we do at the time of discharge, because you have to sign to go to any facility, and it makes sense to discuss this at that time. So, that is the time that we discuss it, and case managers are involved in the discussion. I don't know of a system that has physicians actually discussing the disposition, unless the family has a formal family meeting, case managers are there, physicians are there in that meeting. So, that occurs, not that often, but often enough that physicians are aware of the issue. But, I think we do it at the time of discharge. So, I support the recommendations, as well.

DR. BAICKER: I support the recommendations. I think I was one of the people who thought that it might be more helpful to provide beneficiaries with the information about the implication of an observation stay for their subsequent coverage at that moment where it actually applies as opposed to in the reams of information about all sorts of

things that don't apply that people get at the beginning.

But, I very much defer to my colleagues with more experience in the actual clinical setting about how that would play out. If it's not helpful, then we shouldn't do it and I'm fine with it as written. But, if there were a way to deliver the information at the moment when it's actually salient to people and applies to them, as a naive outsider, that seems like it could be more impactful and contribute less to the check, check, check, check, check mentality that people have when there are those giant clipboards. So, either way on that recommendation would be okay by me as informed by those people who actually know how it works on the ground.

DR. NERENZ: Yeah. I support the recommendations comfortably, and just a side note on Number 4 about the notification. It struck me in reading the chapter, on page 25, there was a point there that really hadn't sunk in to me in all of our prior conversations and that's just the difference in the out-of-pocket expense, inpatient versus outpatient, for something like an 18-hour, 24-hour stay.

You know, it seemed fairly natural to talk to a patient and say, okay, look, you're here for chest pain and

we want to get this sorted out. We don't think you're having a heart attack, but we need to be careful. If we admit you to the hospital, this is going to cost you about $1,000. If we do it as an outpatient, it'll cost you about $200. That's why we're thinking about doing it as an outpatient. I mean, somehow, that would seem to me to be a pretty salient way of explaining the difference.

Now, that's not part of the recommendation, I understand, but it just struck me that if I was going to explain this to a patient, I'd probably try to weave that in there somehow.

MS. UCCELLO: I support the recommendations, and just in terms of the timing of this notice, I'm another naive outsider, but also someone who's had a family member who's gone through this, and I think at discharge is too late. It can be part of the discharge planning process, but at that point, that's too late.

MR. HACKBARTH: Yeah. I'm not sure that this fully addresses Mary's concern, but I think the concept would want to be that the conversation happens before it's too late, and so it can't be as the patient is being loaded into the ambulance to go to the SNF --

[Laughter.]

MR. HACKBARTH: You know, ideally, you'd want the patient to have the opportunity to say, "Oh, I may not be covered if I go to a nursing facility. Can I go home as an alternative to that," and if necessary, for the patient's physician to be involved in making that determination. So, it can't literally be at discharge, as they're being wheeled out of the hospital.

Kate.

DR. BAICKER: And in that spirit, it seems too early to do it when it may or may not apply. You can't ask people to say, now, if this happens, do you want to go here, but if that happens, do you want to go there.

MR. HACKBARTH: Right.

DR. BAICKER: There seems like there's a window where it's applicable and subject to potential decision making.

DR. MILLER: I mean, this is difficult to hit, because if we're talking three- or four-day stays and you're saying it's not the last day, but it's not the first day, you're not leaving a lot of room there in --

DR. BAICKER: [Off microphone.] It's at 1:52.

[Laughter.]

DR. MILLER: Okay. So we've got that all cleared up. But, yeah. I mean, there is --

DR. NAYLOR: [Off microphone.]

DR. MILLER: Yeah, right. But which midnight? The second one?

[Laughter.]

DR. MILLER: And, Glenn and I were talking about this a bit before the meeting started. This is really about the timing, and these stays are not 14 days. These stays are three and four days.

MR. HACKBARTH: Yeah. I'm not sure what the right answer here is, but I'm sure we're having the right conversation. I fear, too often, the notion of beneficiary education is reduced to, well, let's give them another form. And, so, at least we're trying to figure out how to do actual helpful communication of information. That is a good thing in and of itself.

Rita.

DR. REDBERG: So, I support Recommendations 3 and 5. In looking at them, it occurs to me, and maybe I'm either missing something or I should have seen it before,

but if we implemented Recommendation 3, it seems to me Recommendation 4 is kind of irrelevant because it wouldn't count. What?

DR. HOADLEY: [Off microphone.] -- requires the one inpatient day.

MS. UCCELLO: [Off microphone.] You still have to have an inpatient day.

DR. REDBERG: Right. You still have to have an inpatient day, but it really would depend on whether you've had three days or not. It doesn't matter whether you had -- I don't think anyone's going to be in obs status for three days, and so --

DR. MILLER: [Off microphone.] -- some are --

DR. COOMBS: [Off microphone.] Yes. Yes.

DR. REDBERG: Okay. Well, then, this would only apply, I think, to people that would be in obs for three days, because otherwise, if you're going to count the initial obs as an -- whatever, towards the three-day rule, unless you really -- I didn't think we had very many people past three days for obs -- you're going to qualify for the three-day skilled nursing requirement anyway, and so you don't really have to be notified that your first day was an

obs day, but it doesn't matter because we're counting it as an inpatient day and you can still qualify for a SNF.

The real question is, do you qualify? Have you made the three-day requirement or not, I mean, and that, I think, with regard to the timing issue -- you know, the social worker always goes and talks to the patient about what their options are. That's when we should introduce this concept of payment. Patients are very attuned to who's going to pay, and I think that's the time, but not to do it for patients that it's never going to be a question, because it is overwhelming.

And after hearing Stephanie raise the template, I thought, definitely not, because that is not useful and we're already giving patients a lot of things they don't read that are required by JCAHO and other measures, and this would just be one more.

The last thing I wanted to say, because David, I thought, made a great point, is in terms of beneficiary notification. I think we should consider adding a notification about the difference in their copayment, whether they're going to be getting their evaluation in obs status or in inpatient status, because that's a big

difference in copayment and patients are unaware of that.

DR. HOADLEY: So, on Recommendation 3, the three-day -- the modification of the three-day rule -- my preference, as I said, I think, at the last meeting, would still have been to have a slightly broader version that would not require the one inpatient day, that if you have that three day, relatively uncommon, but we were told it's by no means nonexistent, that that should still be adequate to qualify you. Since that's not where most people seem to be, I mean, I'm certainly fine with this as the second-best from my point of view.

On 4, I think there have been a number of useful points, and actually, Rita's is kind of interesting, because, I mean, if we do 3, it does make the 4 problem less, although 3 is going to require a legislative change. Four is something that could be done by the Secretary. So, one reason to have 4 in there is that if Congress doesn't do 3, there could be still progress on 4, even without the result of 3 happening, if that makes sense.

MR. HACKBARTH: I didn't follow that, Jack. I'm sure it's because of me. I'm trying to think about process here, as well. Could you just say that again to make sure -

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DR. HOADLEY: Yeah. So, changing the three-day rule is going to require a statutory change.

MR. HACKBARTH: Right. Correct.

DR. HOADLEY: Changing -- requiring notification presumably doesn't require a statutory change.

MR. HACKBARTH: Yeah.

DR. HOADLEY: So, if Congress does not act to make the statutory change, our Recommendation Number 4 sort of goes to Rita's point --

MR. HACKBARTH: Yeah.

DR. HOADLEY: -- is actually useful, because they could go ahead and do that even without the other changes having been made.

MR. HACKBARTH: I've got you.

DR. HOADLEY: I mean, it does strike me that there's a text that seems to fall into place where we describe what you just described as sort of the right conversation, where we can say, you know, what we don't want -- what we don't mean is one more piece of paper on the clipboard, however colloquially or technically we want to say that.

MR. HACKBARTH: Mm-hmm.

DR. HOADLEY: What we don't mean is just giving it to them literally as they're leaving --

MR. HACKBARTH: Mm-hmm.

DR. HOADLEY: -- that the sweet spot seems to be at the point at which discharge planning is occurring. We don't necessarily have to figure out the right way to write that into a rule to make that happen. We can say, these are the principles that we want that's all in the spirit of this notice.

MR. HACKBARTH: Mm-hmm.

DR. HOADLEY: And then, lastly, I do support Number 5 and I'm glad we're going in this direction rather than some of the options that we talked about the other day.

MR. HACKBARTH: Yeah.

DR. HOADLEY: This is the right way to go.

MR. HACKBARTH: Okay.

DR. REDBERG: Glenn, both 3 and 4 start with "The Congress should require," so --

DR. MILLER: That's right --

DR. REDBERG: -- why are you saying that one's administrative and one's Congressional?

DR. MILLER: Yeah. So, this is where I wanted to pick up, because both of your comments were interrelated. So, let me start with Jack's.

We do have 3 and 4 both triggering off of Congressional action, and the key difference is in order to do the notice as an administrative action, and again, this is territory that if we had years, we could understand it better, and then it gets -- well, I mean, this is administering the program, and again, there's a certain humility of trying to keep in mind what CMS can do and not do in trying to understand those things.

I think there was some concern -- I think our initial take on this was, you do it as a condition of participation and the Secretary can do it. What's the problem? And we discussed that with them, and I think some of the concern was is when you do a condition of participation, it has to apply to everyone. And, so, we had to retreat and kind of come back and say, okay, as a condition of payment, you have to give this notice and made it a Congressional action.

Now, I don't think that disqualifies your comment. I think it is possible to approach this issue

administratively, but we felt like we were hitting speed bumps and so we wanted to do something that we thought we could clearly say. Congress, condition of payment, you have to give this notice.

So, 3 and 4, as Rita picked up on, are actually both Congressional actions. But, you're not wrong-wrong. There probably is an administrative path to the notification, but we did run into some bumps when we were trying to talk that through with CMS, and I don't pretend to be deep enough to give you a definitive answer.

So, just bear in mind, they're both legislative. That was the long way around to that.

The other thing I wanted to ask about Rita's thing, when she was saying, you know, this conversation should occur when the social worker goes and sits with the patient and/or the family, and now -- and you made this point, too -- you now have this inpatient day in there, and so that changes things, and I think it does. And, I'm really afraid to do this, because I don't know where it's going to go, but Stephanie also pointed out that in one of the State laws, it said, by the way, if the person is inpatient, then this notice becomes null and void.

You know, we might want to write something like that down, because I think, you know, the application of this rule does change if you hit the inpatient admission. I mean, your eligibility for SNF changes. We could put some words in like that, unless it just complicates the hell out of things and maybe I shouldn't have brought it up. But, that was the other thought that occurred to me while Rita was talking.

MR. HACKBARTH: So, are -- I see some hands here. Are these in specific response to issues that Rita has raised, or, Bill, you want to just continue around the table? Kathy, are you trying to comment on Rita or Jack?

MS. BUTO: I think so.

[Laughter.]

MS. BUTO: This goes back to the issue of whether or not you need 3 -- or need, is it 4, because of 3, or something like that, and --

MR. HACKBARTH: Let me suggest that we're coming around to you in just a second. Why don't we get Bill in --

MS. BUTO: Okay.

MR. HACKBARTH: -- and just continue down the row, and everybody will get their chance. Bill.

MR. GRADISON: I support this, but in thinking about it, in my mind at least, in a broader context, I've been increasingly of the view that maybe in July or some July, we ought to have a session on taking a look at all these issues -- and I'll be more specific in a minute -- from the patient's point of view alone; for example, with regard to notification, with the nature of notification about the choices with regard to staying with traditional fee-for-service versus ACO versus MA, and at what point should that information be imparted to the beneficiary?

With regard to copays, which is part of this picture, at what point do beneficiaries get informed with regard to their financial responsibilities, depending on which silo they go to? Certain ones involve a copayment; certain ones don't. And more to the point, what should they be? We've recommended, for example, adding a copay for home health. We've recommended some changes in benefit design, which affect the patient.

Pardon me. I may have said this before, but I want to summarize my point because I feel pretty strongly about the fact that we don't really talk -- I don't mean we're not interested in the beneficiaries. That's why we're

here, but we don't talk as much about them sometimes as I think we should.

Robert Benchley was a very popular humorist of many years ago, and he is reputed to have failed to earn his degree at Harvard because he put down to the last minute writing his thesis on the subject of the Great Banks fishing controversy, and the story goes that when he finally got around to it, the night before it was due, he sat down at his typewriter with a bottle of gin and prepared his thesis and changed the title to the "Great Banks Controversy as Seen From the Viewpoint of the Cod."

[Laughter.]

MR. GRADISON: Enough said.

MS. BUTO: That's really hard to follow that.

I guess, first of all, I support the recommendations as they are written.

I do want to point out -- and I don't think we talk enough about this -- that there always can be unintended consequences, and the coupling of observation days with an inpatient day, I think could actually lead to what I call the "woodwork effect," which is more observation stays than otherwise might be there. And I think the 2-

midnight rule already may stimulate some of that, and hopefully, we can comment on that at the end.

But I'm worried a little bit about that, that we sometimes create what should be a good thing for beneficiaries, and it actually ends up being an issue on necessary utilization.

The other thing I'd say is I think there are actually two issues on the beneficiary notification. One is the notification, which is your cost-sharing might be higher, et cetera, and there's also discharge planning which several people have talked about, which does come at the end.

I don't think there is a requirement for discharge planning for patients who have stayed longer than, say, 24 or 48 hours in the outpatient department, and yet some of them do go to home health or something else, maybe SNF care. That's more of a conversation, and that really is a condition of participation. We at least might raise the question of whether given the changing nature of outpatient care, CMS ought to take a look at that, because more than notification, it is actually talking about the different options, not just what your financial liability might be.

So, bottom line, I support the recommendations.

MR. KUHN: I'm fine.

DR. CROSSON: Yes. I support recommendations 3 and 5, as written.

I was one of the people originally with respect to No. 5 who was attracted by the idea of simply allowing hospitals to cover the payments but cap the charges.

But given the amount of money at play here, listening to the arguments, I think the notion of just covering it on a budget-neutral basis makes more sense. It's simpler.

On recommendation No. 4, I wonder if the recommendation now, as written, really captures the discussion we've just had because I think I was hearing from a number of Commissioners, something like let's try to focus this a little bit more on the situation that is likely to actually be a real problem for the beneficiary.

And I think rather than saying -- just a suggestion here, rather than saying that this policy should apply to all beneficiaries placed in outpatient observation status for longer than 24 hours, we might say something like who are under consideration for placement in a skilled

nursing facility, which would narrow the number of individuals a lot and focus it on the situation, now that issue then of exactly what time that should take place, as we said earlier, is kind of complicated.

But we might say in the text, that said, it should take place at such a time that there is time for the individual to consider other options, and in other words, it shouldn't be done getting into the ambulance or getting into the transport vehicle to go to the skilled nursing facility.

But in the actual wording of the recommendation, I think if we pass it the way it's written, it doesn't actually serve the purpose we've discussed.

MR. HACKBARTH: Okay. I think we are complete for now. Based on the conversation, I will come back and talk to you individually with perhaps some modifications in the drafts.

Herb and then Kathy.

MR. KUHN: I just would like to raise one issue that is kind of outside the five recommendations that we have, and so I think we have done a really nice job here of narrowing a set of recommendations to really focus on the problem and not make the system go crazy, but we also know

this is kind of an unusual problem, where there was identified, I think, some people that were riding on the edges and then CMS tried to address this issue, but instead of impacting those folks that they deemed were riding on the edges, it impacts everybody. And I'm talking about the 2-midnight rule. It affects everybody in a significant way.

We don't have any recommendations on the 2-midnight rule, and I don't know if I have a specific one right now. So I would like to just say, if we could put a placeholder in there for now, that maybe we can think about it maybe during the public comment. Some of the public can talk about that. Maybe they can come and engage with the staff to help us think that thing through, but with the set of recommendations that we have here, are we missing an opportunity to really complete and make sure this works as effectively as you can, and should the midnight rule be part of that suite of recommendations that we make?

MR. HACKBARTH: Any reactions to Herb's suggestion?

Kathy.

MS. BUTO: Yes. I support discussing the 2-midnight rule in the text because I think there are -- I

have some real concerns about it.

One concern is that it sets an arbitrary sort of time frame for deemed compliance with a medical necessary requirement, and I have real issues with that when it drives in that direction.

I agree with some comments that, in fact, it provides safe harbor, but I think it might also lead to unnecessary utilization, and it also is being driven by hospitals' concerns that they are going to be audited and penalized. And I think that's the wrong set of concerns to drive admitting behavior, whether inpatient or outpatient.

So I'd really like to see us discuss it. I don't think -- I don't have a recommendation. I guess my own preference would be to go back to the 24-hour rule for observation status, but I realize that we haven't had a lot of time to talk about that. I just feel that it's an area of concern, and it's driving some of these other issues, whether it's the three-day prior hospitalization requirement for SNF care, whether it is the one-day stay formulaic approach, which I think gets complicated by observation status.

So I just raise it. I think it may actually, as

we look at it over time, have generated some utilization because hospitals are concerned that they need that rule that may not have been necessary.

MR. HACKBARTH: So I did not include an explicit recommendation on the 2-midnight rule here because I felt like our package of recommendations worked either with the 2-midnight rule or the 24-hour rule, and I was frankly sort of agnostic between the two. I think each has pros and cons. So that was my thinking in putting together this package.

Herb has made the case for explicitly addressing it, and that could be done either in a bold-faced recommendation or just through more extended discussion in the text.

Let me just focus on the possibility of a bold-faced recommendation. I am not going to hold anybody to this, but could I just see a show of hands of people who think maybe given the prominence of the debate about the 2-midnight rule, maybe we ought to say something formal on the record in the form of a formal recommendation on what we think about the 2-midnight rule? Who would like to see such a recommendation?

[Show of hands.]

MR. HACKBARTH: Again, I am not going to hold you to this. I'm just trying to get a sense of how we allocate our time and effort.

We will count you as a weenie.

[Laughter.]

MR. HACKBARTH: Go on, Dave. Go ahead.

DR. NERENZ: [Speaking off microphone.]

MR. HACKBARTH: So we've got five or so.

DR. COOMBS: And you have three missing.

[Laughter.]

MR. HACKBARTH: Okay. Alice conveniently has their proxy.

DR. NERENZ: Well, just like an index -- I mean, my handling of -- I do think the 2-midnight rule has a lot of problems which seem to perhaps call out for something. I do not know what we say as an alternative, though. That is my hesitation.

MR. HACKBARTH: That is sort of where --

DR. MILLER: I mean, without discussing it with the Chair and given the time and complexity that we would have here, I mean, I think this statement would be more

about no 2-midnight rule, and implicitly, it would be kind of going back to what the status quo was before that, which was kind of a 24-hour rule. But it really kind of depends on the clinician.

So I don't know if we would be saying take the 2-midnight rule and do something else as much as we'd be saying, "We don't think the 2-midnight rule is a good idea," given time and --

MR. HACKBARTH: My sense has been if we were to get rid of the 2-midnight rule, if CMS were to get rid of the 2-midnight rule, some good things would happen, but also some things not so good might happen. And that's the reason for my ambivalence about this.

Given the level of interest expressed in a formal recommendation, maybe what we ought to do is beefing up the text discussion and sort of laying out in a little bit more detail what the pros and cons are. Does that make sense to people?

Okay. That is what we will do.

DR. MILLER: And we can make sure that that gets highlighted in what bounces to you for April, and then you can come into the meeting equipped with, "Well, I could

tone," et cetera, that type of thing.

MR. KUHN: I think that makes sense, and I think also that shows the Commission having a good sense of self-awareness because, as we all know, the 2-midnight rule has currently been suspended, but it is supposed to kick back in on April 1. And I think to be silent on that issue, would you say, "Well, did we just miss this one?" Because we're not hearing much from people now. A month from now, we might be hearing a lot.

MR. HACKBARTH: Okay. Thank you, Zach and Stephanie and Kim. Good work. We appreciate it.

We will now have our public comment period.

If you will hold off for just a second, could I see everybody who wishes to make a comment line up, just so I have a sense of how many we might have?

Seeing no others, we've got one, and I think you know the ground rules, but let me repeat them, anyhow. Please begin by introducing yourself and your organization. You have two minutes when the red lights comes back on. That signifies the end of your time, and I will give my standard reminder that this isn't your best opportunity to provide input to the Commission's work. That is working

with our staff, writing to Commissioners, or providing input on our website.

MS. COHEN: Good morning. My name is Allison Cohen, and I am with the Association of American Medical Colleges.

The AMC appreciates this opportunity to share our views with the Commission this morning on the subject of short-stay policy issues. The AMC commends MedPAC's thorough evaluation of issues surrounding short stays and appreciates the Commission's recognition that these issues do not lend themselves to a simple payment solution without RAC reform.

The AMC strongly supports MedPAC's recommendation to hold RACs accountable for improper claim denials by reducing RAC contingency fees if their denial rate is over a threshold. We do not, however, support recommendations that would undermine physician judgment and discourage innovation by targeting hospitals with penalties solely because they have more short inpatient stays than other hospitals because they efficiently treat the sickest and most complex patients.

It is not reimbursement that governs physicians'

admission decisions; rather, it is physicians' clinical judgment of what is medically necessary for the patient. The AMC believes short inpatient stays should be reimbursed as inpatient stays if the physician believes that admitting her or her patient would best serve the particular patient's medical needs.

The AMC also agrees with MedPAC's assessment that new short inpatient stay payment policies would reduce the differential between outpatient and inpatient payments and would create differential payments in other areas. Implementing a new short-stay payment policy without RAC reform would simply shift RAC focus to these new differentials and would not reduce improper RAC or the PL's backlog. This backlog must be reduced, and hospitals must not be penalized for admitting patients whose medical needs demand inpatient care.

Thank you for this opportunity to present our views.

MR. HACKBARTH: Okay. We will adjourn for lunch and reconvene at 12:45.

[Whereupon, at 11:38 a.m., the meeting was recessed, to reconvene at 12:45 p.m. this same day.]

AFTERNOON SESSION [12:46 p.m.]

MR. HACKBARTH: Okay. It is time for us to start up again. Under our revised schedule, we've got two sessions this afternoon, the first on Part B drug payment policy and then one on synchronizing payment across models.

So, Kim, the ball is yours.

MS. NEUMAN: Today we're going to discuss two Part B drug issues that Commissioners have expressed interest in exploring. The first issue relates to the payment methodology for Part B drugs, which is the average sales price plus six percent. The second issue relates to Part B drugs in 340B hospitals.

So the presentation will be structured as follows: First, I'll provide some background on Part B covered drugs and the average sales price payment methodology. And then I'll present some exploratory work looking at alternatives to the 6 percent add-on to ASP that incorporates a flat add-on.

Next, Ariel and Dan will provide background on the 340B drug pricing program and discuss estimates of 340B discounts and Medicare payments for Part B drugs in 340B hospitals.

Before we get started, we would like to thank Joan Sokolovsky, Nancy Ray, and Julie Somers for their contributions to this work.

In 2013, Medicare spent more than $19 billion on Part B drugs administered in physician offices, hospital outpatient departments, or furnished by suppliers. Mostly, these are drugs or biologicals that are infused or injected in providers' offices. A few examples are drugs for conditions like cancer, rheumatoid arthritis, and macular degenerations.

A few types of drugs furnished by suppliers are also covered by Part B, for example, inhalation drugs administered via a nebulizer and a small number of oral drugs.

Medicare pays providers for most Part B drugs at a prospective rate which is equal to 106 percent of the average sales price.

Concern has been expressed by Commissioners, as well as some in industry, that the 6 percent add-on to ASP gives providers a financial incentive to prescribe higher-priced drugs. I'll talk about that in more detail shortly, but first a little a background on what ASP is.

ASP is not the actual price an individual provider pays for a drug. Instead, the ASP for a drug is the average price realized by the manufacturer for sales to all purchasers (with a few exceptions) net of rebates, discounts, and price concessions.

Manufacturers report ASP data for their drugs to CMS quarterly. The ASP plus 6 percent payment rate has a two-quarter lag. For example, the ASP payment rates in effect today -- in other words, first quarter 2015 -- are based on ASP data for third quarter 2014.

So now, getting to the issue of whether the 6 percent add-on to ASP incentivizes use of higher-priced drugs. There is not much research looking at whether the 6 percent add-on is influencing prescribing patterns. In your paper, we discuss a study by Jacobson and colleagues who found that when Medicare moved to the ASP payment system in 2005, the use of the highest priced lung cancer drug increased modestly.

Conceptually, a 6 percent margin on Part B drugs may incentivize the use of higher priced drugs as a 6 margin on a higher price would generate more profit than a 6 percent margin on a lower price.

However, a provider's actual margin on a Part B drug is not necessarily 6 percent. It may be higher or lower than 6 percent, and it could also be negative. This is because the price providers pay for a drug may differ from the ASP used to set the payment rate, and there are several reasons for this.

First, remember ASP is an average, and there is variation in a drug's price across purchasers. For example, if manufacturers offer volume discounts, small purchasers may pay more than large purchasers for the same drug.

Second, there is the effect of price changes and the two-quarter lag in the ASP plus 6 percent payment rates. If a drug's price increases, the provider's margin on that drug will be reduced until ASP catches up. On the other hand, if a drug's price decreases -- for example when a drug goes generic -- providers may earn a large margin on a drug for several quarters.

Another factor is prompt-pay discounts, and here's how that works. Manufacturers sell drugs to intermediaries like wholesalers, and then wholesalers sell the drugs to physicians and hospitals. If the wholesaler pays the manufacturer quickly, the manufacturer may give the

wholesaler a prompt-pay discount, reportedly in the range of 1 to 2 percent. These prompt-pay discounts lower ASP because they reduce the price ultimately realized by the manufacturer. Providers and wholesalers report that prompt-pay discounts are largely not passed on from wholesalers to providers. So this means the average price providers pay for a drug could be slightly higher than ASP because of prompt-pay discounts. We can walk through this more on question if you'd like.

In response to your interest in the ASP add-on issue, we have done some exploratory modeling to look at the implications of converting the 6 percent add-on to ASP to a flat add-on. And today we have two policy options to look at. Both were modeled to be budget neutral to ASP plus 6 percent assuming no utilization changes.

The first option is 100 percent of ASP plus $24 per drug administered per day. This option fully converts the 6 percent add-on to a flat fee.

The second option we modeled is 102.5 percent of ASP plus $14 per drug administered per day. With this option, the thinking is that you may want to consider maintaining some portion of the percent add-on given the

things we just talked about like prompt-pay and price variation across purchasers. So with this option we tried to strike the balance between some percent add-on, but still a substantial flat fee. This, of course, is illustrative. Other budget-neutral combinations of percent add-ons and fixed fees could be explored.

One final thing to keep in mind: All of our modeling focuses on the pre-sequester payment rates.

So this chart shows you what happens to the payment rates for differently priced drugs under current policy compared to these two options.

The price of the drug as measured by ASP per administration is in the first column of the chart.

So first in that sort of light-yellow circle there, you can see that we have a low-priced drug, a drug that costs $10 -- has an ASP of $10 per administration. And what we can see in that circle is that, under current policy, 106 percent of ASP, that drug would be paid $10.60.

If instead the drug was paid under Option 1, 100 percent of ASP plus $24, the drug would be paid $34.

And then, alternatively, under Option 2, the drug would be paid $24, roughly. And so this shows you that for

a low-priced drug, a flat add-on would increase payments.

And now if we move over to the two columns on the left, these columns express the payment rates we just discussed as a percentage of ASP, and so you can see that Option 1's payment of $34 is equivalent to a payment rate of 340 percent of ASP. Option 2's payment of about $24 is equivalent to about 242 percent of ASP.

So now if we go to the bottom of the chart, we are looking at a very expensive drug, a drug that has an ASP per administration of $5,000. And so what we see here is that the flat add-on is going to decrease payment for these drugs. So, for example, under current policy, a drug with a $5,000 ASP would be paid $5,300. If instead you had a flat add-on as shown in Option 1, that drug would be paid $5,024. Or under Option 2, it would be paid $5139.

And then if we go to the far right of the chart, we can see that Option 1's payment of $5,024 is equivalent to a payment of 100.5 percent of ASP. Option 2's payment of $5,139 is equivalent to a payment of 102.8 percent of ASP.

So as we saw on the last slide, both policy options that incorporate a flat add-on would increase the payment rates for low-priced drugs substantially.

In terms of the effect on provider's incentives, the increase in the payment rates for low-priced drugs may create more incentive for the substitution of low-price drugs for high-price drugs where therapeutic alternatives exist.

It is also possible that a relatively high margin on inexpensive drugs could create incentives for overprovision of these drugs among some providers.

As far as expensive drugs, an important question is whether providers would be able to obtain these drugs within the Medicare payment rate.

Under Option 1, 100 percent of ASP plus $24, providers might have difficulty purchasing some very expensive drugs within the Medicare payment rate. This is because for very expensive drugs, the payment rate under this option is close to 100 percent of ASP. Given prompt-pay discounts and price variation that we talked about earlier, it is not clear whether many providers would be able to purchase very expensive drugs at a price near 100 percent of ASP.

Under Option 2, 102.5 percent of ASP plus $14, it would be more likely that providers would be able to

purchase very expensive drugs within the Medicare payment rate. Some small purchasers, though, might not. But that will depend on how drug manufacturers respond to the payment changes. For example, following implementation of ASP plus 6 percent in 2005, manufacturers responded by reducing price variation across purchasers. It is possible that manufacturers might further reduce price variation across purchasers if Medicare changed its payment to include a flat add-on.

One last point, as I mentioned earlier, it's important to note that all of these estimates are based on pre-sequester payment rates.

A flat add-on would redistribute revenue across providers. Payments would increase for suppliers and physicians overall, while payments would decrease for outpatient hospitals and certain physicians specialties.

For example, under Option 2, Part B drug revenues for physicians would increase by eight-tenths of a percent. For physician specialties that tend to use expensive drugs -- oncologists, ophthalmologists, and rheumatologists -- Part B drug revenues would decrease by 1 to 2 percent, while Part B drug revenues would increase for primary care physicians

and other specialists by roughly 6 to 7 percent.

Hospital outpatient departments would also see a revenue decrease of about 2 percent, and suppliers would see a revenue increase of more than 4 percent.

Now I will turn it over to Ariel and Dan to talk about 340B hospitals.

MR. WINTER: So we discussed the 340B program at our November meeting, and at that meeting,

Kate asked about the difference between Medicare's payment rates for outpatient drugs and the prices paid by 340B providers to obtain those drugs. And Kathy asked us to think about the interaction between Medicare payment rates and the 340B program.

So, first, we'll start out by reviewing some background on the program.

The 340B program allows certain hospitals and other health care providers (known as covered entities) to obtain discounted prices on most outpatient drugs from manufacturers. The program covers outpatient prescription drugs and biologicals, other than vaccines.

Covered entities include disproportionate share hospitals, critical access hospitals, certain other kinds of

hospitals, and certain clinics that receive federal grants.

The discounts available through the program for outpatient drugs are comparable to Medicaid's drug rebates. These discounts apply to drugs used for uninsured patients as well as for patients with Medicare and commercial insurance.

As we showed in November, the 340B program has grown rapidly since 2005, both in terms of spending on outpatient drugs and the number of covered entities.

The significant growth in the number of 340B hospitals since 2010 has been driven by the program's expansion under PPACA.

Medicare Part B pays for outpatient drugs provided by 340B entities to beneficiaries.

Under the Outpatient Prospective Payment System, Medicare pays the same rates for drugs to 340B and non-340B hospitals, even though 340B hospitals can buy outpatient drugs at a steep discount.

Spending by Medicare and beneficiaries for Part B drugs at 340B hospitals grew from $0.5 billion in 2004 to $3.4 billion in 2013.

The Health Resources and Services Administration

manages the 340B program and sets ceiling prices for each outpatient drug. The ceiling price is the maximum price a manufacturer can charge for a 340B drug. And, therefore, it plays a major role in determining the acquisition costs and discounts for 340B drugs.

The ceiling price is based on same statutory formula used to calculate Medicaid drug rebates, and HRSA is legally prohibited from publicly disclosing these ceiling prices.

So we tried to quantify the discounts on Part B drugs for 340B hospitals. I'll be talking about our approach today at a relatively high level, but there's more detail in your paper, and we'd be happy to take questions about that.

To precisely calculate the discount, you would need to know average manufacturer price, or AMP, as well as the best price for each drug, both of which are confidential.

So we approximated the average discount by using ASP, which is public, as a proxy for AMP and applying the minimum statutory rebate for each type of drug, which is 23.1 percent for brand drugs and 13 percent for generic

drugs. This yielded an average discount for 340B hospitals of 22.5 percent of ASP.

This is a weighted average of the rebate for brand and generic drugs, and we'd be happy to discuss the method that we used to reach this in more detail if you have questions.

It is important to emphasize that our estimate of the discount for Part B drugs under 340B is the lower bound of the actual discount. In other words, this is a conservative estimate, and that is for the following reasons:

First, AMP is usually higher than ASP, and because we're multiplying 22.5 percent by ASP instead of AMP, our estimated discount is smaller than the actual discount.

Second, we don't have access to the best price data, and the actual discount formula takes into account the manufacturer's best price for a drug.

Third, without AMP data, we cannot calculate the inflation rebate, which is added to the discount if AMP has grown faster than inflation since drug's market date.

And, fourth, there is a HRSA contractor that negotiates steeper discounts -- below the ceiling price --

on certain drugs.

So now that I've given you these caveats, Dan will discuss the results of our analysis.

DR. ZABINSKI: We created this table in response to the question that Kate asked last November. It shows the difference between how much 340B hospitals are paid by Medicare for drugs provided in their OPDs and how much we estimate those hospitals paid to acquire those drugs in 2013.

Remember that we overestimate acquisition costs, which is ASP less the 340B discount we estimate for the drug, which Ariel just covered.

Note that this table excludes the critical access hospitals that are in 340B because their drug payments are based on cost rather than ASP plus 6 percent, as they are for other hospitals.

We also excluded the 340B hospitals for which we don't have Medicare OPD revenue or overall Medicare revenue.

The first column in the table lists the Medicare OPD drug revenue, which is $3.2 billion for all of these 340B hospitals.

The second column lists our upper-bound estimate

of the acquisition costs for these drugs, and the total for the hospitals in the table is $2.4 billion.

Columns 3 through 5 are based on the difference between the revenue in Column 1 and the cost in Column 2. This difference between revenue and cost reflects our estimate of the 340B discount plus the 6 percent add-on that the hospitals receive that Kim has already discussed.

In dollar terms, the difference between the revenue and cost is $0.8 billion for the hospitals in this table. Some hospital categories account for a fairly large share of this difference, particularly urban hospitals and nonprofit hospitals, and to a lesser extent major teaching hospitals.

The fourth and fifth columns show revenue minus cost as a percent of Medicare overall revenue and Medicare OPD revenue, respectively. Revenue minus cost is about 1.1 percent of Medicare overall revenue and about 4.5 percent of Medicare OPD revenue for 340B hospitals.

Among hospital categories, there is not much variation in revenue minus cost as a percent of overall Medicare revenue. But, in contrast, there is a fair amount of variation in revenue minus cost as a percent of OPD

revenue, from about 3 percent for rural hospitals to nearly 6 percent for major teaching hospitals. This difference is due to OPD revenue being a relatively large share of overall revenue for rural hospitals and a relatively small share for major teaching hospitals.

So as part of your discussion today, please let us know of any clarifications we can provide. Also, let us know of any additional information you would like. For example, we've done an analysis of 340B hospitals, but there are many other providers in the 340B program, such as FQHCs, and for future work we can analyze these providers as well.

We also seek reactions to the policy options for the 6 percent add-on that Kim discussed and any ideas that you may have for policy options in the 340B program.

I'll turn it back to Glenn.

MR. HACKBARTH: Okay. Thank you all.

Just a word about where we are in the process of this. I think the plan is that we will include a chapter in the June report discussing these issues. We are not yet close to the point of making recommendations. So if we, as a group, elect to pursue recommendations, that would happen next cycle, not this one.

Let me click off the clarifying questions, if I could, Kim. Would you put up Slide 8.

I am focused on the bottom half of Slide 8, these last couple bullets, and in particular, that last bullet, the reference to relatively large margin, I am inferring as a reference to the preceding table, so could you go to Slide 7.

I assume that is a reference to these last two columns in Slide 7, which shows the payment rates as a percentage of ASP. My question is, are those really depicting the margin, which to me means profitability, to the provider of those different drugs?

To me, the margin would be a function of what the costs are, and you would need to know what the amount paid for the drug is and the amount of administration, the cost of administration.

In the example of the $10 drug, it may be that that person, that physician practice, has paid $10 for the drug, and their cost of administration is $24 or $14, and so their net margin is zero. But if you express the payment as a percentage of ASP, it looks like, "Oh, this is a really profitable drug." I am not seeing this really as a

representation of what the profit is to the provider.

MS. NEUMAN: Two things, and I should have said this from the outset. These are the drug payment rates modeled here. There is a separate payment that's made for administration, either under the physician fee schedule or the outpatient perspective payment system.

When thinking about just the margin on the drug itself, what I meant here is that you could have a drug that is $2 in terms of ASP. Let's just pretend. And maybe they don't even get it for $2. Let's say they got it for $3. If you are paying an add-on of $24 or $14 on top of ASP, would that create incentives for people just to throw another one in? Not everybody, but would there be some incentives for overuse? It's a question.

MR. HACKBARTH: Yes. I see your point, and I had lost focus on the separate administration payment, which does alter this. I understand what you are saying.

DR. COOMBS: Glenn, could I ask a question?

MR. HACKBARTH: Yes. Sure.

DR. COOMBS: This is a thing that bothered me as well.

So the facility charge -- a patient comes in for

IVIG or something like that. The facility charge is totally separate in the OPD, and this is strictly for the cost of the drug. So you are not including anything with administration for facility charges.

MS. NEUMAN: We just focused on the payment for the drug itself and did not focus on the separate payment for administration that occurs.

MR. HACKBARTH: Is it on this same issue?

Kathy and then Jay.

MS. BUTO: Glenn, I think back to your point, though. Aside from the administration cost, the 6 percent is currently supposed to go for things like storage, handling, some of the things associated with the drug itself, and so I think your point is still well taken, which is if it costs you $20 to store and keep an inventory of drugs, and are you just breaking even versus something gives you $1,024, for example? So I think that point still holds. It is not for the administration but for what the 6 percent was supposed to go to, I think, right?

MS. NEUMAN: We talk about this a little in the paper. There is definitely a view that the 6 percent is to compensate for storage or handling, but there is also other

views, that it's to take care of price variation or to deal with prompt pay or to deal with a lag, and there has never been any consensus on what the 6 percent is really for.

MR. HACKBARTH: Jay and then -- Bill, is your comment on this particular issue as well?

Okay. Jay?

DR. CROSSON: I had the same point as Kathy. We tend to think about margin in terms of percentages; whereas, this is supposedly paying for some set of costs that the physician has. At the $10 drug, they get 60 cents to deal with that, and the $5,000 drug, they get $300. I think the point you were making, as Kathy said, is valid, but mostly, when you think about it in terms of dollar terms rather than percentage.

DR. HALL: You had a paragraph in the written material where you said, "We don't really know what the 6 percent covers," that there are a lot of different theories which suggest that we really don't know what it's for.

A very informal survey I did around my own medical center, I could not find one physician that knew what I was talking about when I said --

[Laughter.]

DR. HALL: Then they just reflect the kind off rural place where I live.

But I don't think that the idea of a physician gaming the system is really the issue here. I think it's a much more global issue of manufacturers and purchasing departments.

It is probably incredibly oversimplified to say that it costs more to give a pill that's expensive than a pill that's cheaper. Is that -- I'm searching for some -- before we either keep this or destroy it, I'd like to really know what it is that we are trying to fix here.

MS. NEUMAN: The idea that the cost of providing a drug is associated with its price, it's not clear that that's the case. There may be drugs that have very handling costs, and whether that's really correlated with our cost or not is really unclear and questionable, I think is what you're implying. So if that is what the 6 percent is intended for, then that's exactly the point.

DR. HALL: Okay. Thank you.

DR. MILLER: Yes. I think the problem -- and I think it's a completely fair question -- whatever the 6 percent was intended for, whether it's the distribution

around the numbers, so some people argue strenuously, you added the 6 percent because everybody can't buy it at ASP, some above, some below, you need it to give some play, I think some of the arguments came along later that it was storage and that type of thing.

But whatever it is, I think -- and perhaps the choice of margin was not clear. I think the point that Kim is trying to illustrate is look what happens as you walk up the price of the drug, and that's what I think she's focusing on.

And the question is, currently, it works the other way. Where the money, the add-on is very high at the high-cost drug, you can start to walk down this road, which was raised by the two questioners, but then you switch the dynamic and how much do you want to switch that dynamic is the question.

MR. HACKBARTH: Perhaps one thing that we might be able to say on this is that if the notion is that the 6 percent is for the cost of handling and those issues, it really does seem like it may be problematic as a way to properly compensate for the cost of those activities. I don't think there is any reason to believe that they are

directly proportional to the average sales price of the drug.

If in fact the 6 percent is not for that but because of variation around the average, it would be nice to see that variation documented.

Now, I know that we won't have access to that information, but perhaps that's a good piece of work for the IG or the GAO, somebody who can basically command that information to take a look at.

But just to sort of acquiesce, 6 percent without a clear rationale, I don't know. It seems a little odd to me.

MR. HACKBARTH: Okay. So --

DR. MILLER: Can I just say one other thing? The other thing -- and this is -- your point stands. The other thing is whatever policy anybody picks here, that variation around it will change. There was some documentation that when the ASP-plus 6 showed up, the variation around ASP crunch, if you changed it to 4 or 2 or something like that, you would expect the variation to change again. So it is going to be a bit fluid.

MR. HACKBARTH: Okay. That was a clarifying question.

[Laughter.]

DR. MILLER: Sorry about that.

MR. HACKBARTH: Now we're open to two other clarifying questions. We'll start with Jon and go down this way.

DR. CHRISTIANSON: So this really is helping me clarify.

The notion of going to the flat rate, as I understand, is just assume for the moment that the administration costs, whatever, are the same, whether you're doing a low-price drug or a high-price drug. You are making the same profit for doing one or the other. Forget margin right now. The amount of money you get from administering the low-price drug profit -- let's assume the 6 percent is profit now or some portion of that. That is equal, depending on which drug you choose, and so the only way this kind of nudges you towards the cheaper drug is the time cost of money, in the sense that you have spent a lot more money on inventory for the high-price drug, and that money is tied up. So you would be more inclined to want to go to the low-cost drug.

So with a percentage, then the slide makes less

sense to me than just saying if the activity is the same in each case and the profit you make is the same in each case, then you've essentially taken away the incentive to overprescribe the high-cost drug and maybe even nudged you towards the low-cost drug because of the time cost of holding inventory.

Would you agree or disagree with that notion?

MS. NEUMAN: I think if you're acquiring all of these drugs at ASP, then, yes, for the time cost of money argument, I would agree. It would nudge you toward the cheaper drug.

DR. CHRISTIANSON: Yes. Well, I find the profit margin discussion, like other folks, a little bit confusing here.

MS. NEUMAN: And I think just to clarify, the reason that we have those percentages on the screen is because it gives you a sense of how close you're getting to paying for ASP, and because of the issues with prompt pay and with price variation and the lag, there is some question about whether people really get it for ASP. And so that just gives you a sense of how close you're cutting it and a judgment about whether you're comfortable or not.

DR. CHRISTIANSON: Fair enough.

MR. HACKBARTH: Alice.

DR. COOMBS: Table 5 in the handout material.

As I look at that, it tells you, basically, aggregated data. Is there any way to look at what happens when you drill down -- and I know this is probably asking a lot per capita of revenue cost data -- just to look at margins that might exist or advantages that might exist with the different entities that are on that chart? I mean, I understand the 340B discount and the impact it may have.

One of my concerns is that, as you know, you get to higher-priced units, that it doesn't necessarily justify -- there is not a direct correlation with the cost of the drug and the cost of giving the drug or the cost of storage.

MS. NEUMAN: Are you referring to Table 5 in the paper or --

DR. MILLER: Slide 5.

DR. COOMBS: In the paper. I'm sorry. Page 22.

DR. MILLER: I'm sorry. I got distracted. The table, can you just hit us again?

DR. COOMBS: On page 22 is Medicare revenue estimated drug acquisition cost and estimated discounts for

340B hospitals from OPPS-covered drugs, and so my question was -- this is all aggregated data, and I am wondering if there's some clear advantages to the different categories here versus -- in other words, the accumulative market share of how an academic or non-profit, for-profit -- I would imagine the bed size of the hospital and advantages that they may share differentiates the kind of revenue that is generated.

So we have aggregated data, but we have no units which those abide by.

DR. MILLER: And the disaggregation that you are looking for is by the provider or by the drug?

DR. COOMBS: Probably by the drug.

DR. MILLER: So your point is if even the two hospitals of the same kind, if they had a different mix, would their advantage under the discount be different. Is that kind of what you are asking?

DR. COOMBS: [Nods head in the affirmative.]

DR. MILLER: All right. I'm sorry. It took me just to get there.

I am thinking our capability to get below this is relatively limited because we're making a pretty gross

assumption across the board here.

Gentlemen?

DR. ZABINSKI: Well, no.

DR. MILLER: Oh, okay.

DR. ZABINSKI: We have drug-level information.

DR. MILLER: Go ahead.

DR. ZABINSKI: Okay. And the unit rebate rate, it is 23.1 percent for brand drugs -- and it doesn't matter which drug it is -- and 13 percent for generic drugs.

Now, most of the drugs in the study were brand drugs, and that is why you get the 22.5 percent. That is very close at 23.1 percent. So I don't see any advantage accruing to any particular type of drug or provider because of that.

DR. COOMBS: So my question was, is there more than one discount? For instance, the quick-pay discount and other advantages that these entities may have when you drill down to individual data, are you able to capture some other kind of advantage of larger institutions?

MR. WINTER: Oh, okay. Maybe you are asking whether -- so the ceiling price is the same for all drugs, all 340B entities, but it is possible for -- it is possible,

perhaps, for larger entities or collections of entities to negotiate below that ceiling price, and there is a vendor hired by HRSA to manage distribution of these drugs called "Apexus," which says it negotiates sub-ceiling discounts of certain drugs by pooling the purchasing power of lots of providers. But we have no access to that data.

All we can do, we can tell you what the formula is for the ceiling price, and we can estimate to a very sort of conservative estimate to what that discount equates to, as we talked about here in the paper, but we can't tell you exactly what the ceiling price is, and we certainly can't tell you what the actual price paid by each of those hospitals is. But it cannot be higher than the ceiling price. It can only be lower.

I don't know if you're asking about the relative impact on different categories of hospitals, but in Slide 16, if you don't mind putting that up, you can see how the impact varies by different types of hospitals. So it's a bigger impact for -- what is it? -- major teaching and urban hospitals. Sorry. It's hard for me to see from here. Yes.

DR. COOMBS: I understand.

MR. WINTER: I don't know if that helps answer

your question, but we did try to look at the impact on different categories of hospitals of the 340B program.

DR. MILLER: But there's almost more -- and I want to say this carefully, Dan. I thought you said something along the line when you were talking about this, that's probably almost more of a denominator effect of like how big the outpatient department is overall as opposed to something about the mix or the discount.

DR. ZABINSKI: Yes. I think you are right.

DR. MILLER: All right. It means a lot to me when Dan says I'm right because, usually, when I say something, he says no.

[Laughter.]

MR. HACKBARTH: Okay. We are on clarifying questions.

Does it relate to this particular discussion, Jon?

DR. CHRISTIANSON: I think so.

[Laughter.]

MR. HACKBARTH: You say that with a lot of conviction.

DR. CHRISTIANSON: I got a little confused about the discussion.

DR. MILLER: See if you can sell it.

DR. CHRISTIANSON: I'll try.

So are we assuming that when hospitals by drugs under the 340B plan and Medicare beneficiaries use drugs in that hospital that were bought under the 340B plan that they are using drugs at that lower price? There's not two ways to buy drugs in those hospitals, one for Medicare patients at a higher price and one for other patients at a lower price? Are they just whatever the lower price is, they use that drug for Medicare?

MR. WINTER: Presumably. Presumably.

DR. CHRISTIANSON: So we are essentially overpaying -- we are all overpaying for all Medicare patients in that hospital? That is the assumption?

MR. WINTER: Our assumption is that they are using 340B drugs for all of their patients, commercial, Medicare, and uninsured. Medicaid, it gets a bit more complicated, and we can talk about that, if you want, but for Medicare, we assume --

DR. CHRISTIANSON: So you are saying Medicare issue to the extent we think that is not right. I mean as a group, we think that is not the way it should be? Is that

what we're saying?

MR. WINTER: That is for your to discuss.

DR. CHRISTIANSON: Right, right. But the issue is as I --

MR. WINTER: Yes.

MR. HACKBARTH: Will the Medicare payment go down when the acquisition cost is pushed down by --

DR. CHRISTIANSON: Yes. Among all the detail, I didn't want us to lose --

MR. HACKBARTH: Yes. Okay.

So we are going down this side, clarifying questions. Dave and then Cori and Jack.

DR. NERENZ: Well, actually, what I may do is try to clarify Alice's question, just so I understand, because I hadn't thought to go that way, but I thought, well, maybe there is some rich territory, if I understand the territory.

So let's take, for example, two teaching hospitals, same category, same size one. One has a really big oncology program; one doesn't. The big oncology program will probably generate more 340B margin, whatever noun we use, just because there is more drug in play.

Okay. then another step, if the big oncology

program uses within its choices, a lot of really expensive drugs that are purchased at 340B prices, they will even generate more margin. Is that kind of --

DR. COOMBS: That's correct.

DR. NERENZ: Okay. I just was trying to work through an example of what that was about.

MS. UCCELLO: Well, I think I have a much simpler question that I probably should be embarrassed to ask, but I'm not.

[Laughter.]

MS. UCCELLO: The unit, per drug administered per day, what exactly does that mean? If you have the same drug twice in a day versus a different dosage of the drug twice, at different times of the day -- how does that work?

MS. NEUMAN: So --

MS. UCCELLO: And you can tell me it was actually a really good question.

[Laughter.]

MS. NEUMAN: It's an excellent question.

[Laughter.]

MS. NEUMAN: So, we had to make a decision on how to model this, and so what we decided to do for these

purposes was for each incidence of a beneficiary receiving a unique drug on a unique day, we modeled the flat fee as going toward that. And, so, if it happened in your example that they got it in the morning and then they went back and got it in the evening, in our model, just one flat fee for that drug on that day.

MS. UCCELLO: But if the dosages were different, it still --

MS. NEUMAN: Right. It doesn't --

MS. UCCELLO: It doesn't matter.

MS. NEUMAN: Doesn't matter.

MR. ZABINSKI: I just want to add, that makes it consistent. I'm not sure about the Physician Fee Schedule, but in the outpatient PPS, the one-day cost -- that's the basis for the payments in the outpatient PPS. It probably is the same in the Physician Fee Schedule, too. So, it makes a nice consistency.

DR. MILLER: Everybody's probably up to speed on this, but as long as we're asking simpler questions -- which, I actually don't think that was a dumb question at all -- most of this is injection stuff, infusion stuff, as opposed -- all right. Everybody's good.

MR. HACKBARTH: Okay. Clarifying questions. Rita, and then Jack.

DR. REDBERG: I have several clarifying questions, Glenn.

MR. HACKBARTH: Come on, Rita.

DR. REDBERG: Okay. On Table 1, page three, can you give us a few examples of the drugs that were in that $5,000 category, like, specifically. I understand they're for cancer and rheumatoid arthritis and macular degeneration, but were there some that --

MS. NEUMAN: So, I don't know if it would be a good idea for me to quote the names of cancer drugs, because the line between the $5,000 and the $2,000 to $4,900 category, I might get that wrong on the spot.

DR. REDBERG: Mm-hmm.

MS. NEUMAN: Probably an easier example would be to say clotting factor. That's extremely expensive per administration, and that would fall into the $5,000 category.

DR. REDBERG: Thank you.

And, the other question was related to the HRSA policy of not being able to publicly disclose the prices of

the -- the ceiling prices, and also not knowing the average manufacturer price. So, what is the -- that's by regulation, and what is the reasoning behind that?

MR. WINTER: Statute. It's in statute.

DR. REDBERG: And what's the reasoning for keeping that secret?

MR. WINTER: It's sensitive information.

[Laughter.]

MR. WINTER: That's my guess. I --

DR. REDBERG: Sensitive to know what they're paying?

MR. WINTER: It actually goes to the manufacturers. But, however -- let me just back up a second. So, the ceiling -- I believe it's in statute that HRSA cannot publicly disclose the ceiling price. AMP, it's a bit different. The DRA of 2005 required CMS, the Secretary, or CMS, to put out all the AMPs on a publicly accessible website. However, this is not -- CMS has not done this and we don't understand why. But, it is in statute that AMPs are supposed to be public, and Jack is shaking his head, so maybe he knows why, so that's the AMP. And ceiling price, there's no provision in statute for those

to be publicly available.

DR. REDBERG: I just don't think price is proprietary, not when you're paying.

MS. BUTO: -- be able to -- I don't know if I can shed any light on this or not, but I do know that in the conservation of the drug benefit, there was at one point a provision -- Jack, you might remember -- that would require PBMs to disclose the discounts they were getting on drugs, and, I think, prices, and CBO scored that as a cost, because that would do is behaviorally cause prices to flatten out. Maybe Kate knows. Some economist can bail me out here. But, there was an actual study to look at the behavioral effects of doing that. I don't know if that has anything to do with this. If there's a requirement already in the statute to publish AMPs, I would think they at least got over that issue for AMPs. But, I could see why that might have an influence on whatever discounts HRSA thinks it can get below the AMP and being concerned they wouldn't be able to get as good a discount if they published the discount rates.

MR. HACKBARTH: So the --

DR. REDBERG: The VA publishes prices of what they

pay for drugs, right, and they get good prices.

MS. BUTO: Yeah, but those are largely, or at least partially, formula driven.

DR. HOADLEY: I think where it's formula driven, they've published. I'm not sure they always publish the additional negotiated discounts, and that's usually where -- I mean, the reason, presumably, AMP was supposed to be made available, those are averages, so you're not revealing any one manufacturer or any one purchaser's price, which is what some, at least, view as proprietary, and if revealed, would affect the market.

MR. HACKBARTH: The notion is that if those discounts are public, that the drug company would be less willing to give a deep discount because everybody would line up at the door and demand the same number.

DR. HOADLEY: That's the logic that's typically cited. Whether it's an accurate assumption or not is --

DR. MILLER: Or empirically tested.

MR. HACKBARTH: Yeah, and it's a rationale that ensures often having gag orders on negotiated prices with providers, sort of the reverse.

MS. BUTO: There's a very old CBO study on the

impact on pricing of Medicaid best price --

DR. MILLER: [Off microphone.] Yeah --

MS. BUTO: -- that addresses this issue, but it's really old, and I don't think anyone has gone back and redone it.

DR. MILLER: [Off microphone.] I know the study.

MR. HACKBARTH: Yeah. Okay. So, continuing with clarifying questions. Jack.

DR. HOADLEY: So, on Slide 10, I just wanted to be clear that on these impacts in different physician groups, these are the percentage effect on their Part B drug revenues, not overall, and so, presumably, the oncologist or the ophthalmologist, some of the groups that do a lot of this kind of drug, this is on a much, much bigger basis than, say, for a primary care doctor who doesn't administer a lot of total -- I mean, it would be interesting to see sort of what the volumes underneath those are to be clear, because I was surprised by, like, the 6.5 and 7.5, but I'm thinking that's on a very small base.

MS. NEUMAN: In your paper on page 11, you can see the base for some of these categories.

DR. HOADLEY: Okay. Okay, good. I'll look at

that later.

And then, in the paper, you had talked about the different formula that's used on the biosimilars where it's a percentage of the original drug rather than the percentage of the actual price for that biosimilar. I assume if we pursued these options further, you could sort of use a parallel for those along the line, so if you went to flat, obviously, it's flat. But, if you went to the sort of hybrid, you could still do the percentage based on the original biological or something like that. But, you haven't touched that so far in this analysis, I assume.

MS. NEUMAN: We haven't, but you could certainly think about that.

DR. HOADLEY: Yeah. Okay.

MR. HACKBARTH: Okay. On this side, clarifying questions. Any? Bill, and then Kathy.

MR. GRADISON: Some years ago, I did some work with a consulting pharmacist. These are the folks that provide pharmaceuticals for nursing homes. My recollection at the time was that most States in their Medicaid programs provide a flat dispensing fee, and that's it. I'm not sure it's relevant. I appreciate the distinctions and all that.

But, I just wondered whether that sheds any light. I don't even know what the current facts are, because it's been a while.

MR. WINTER: So, OIG did a study a few years ago of how Medicaid programs pay 340B providers for drugs, and I think this is what your question might be getting at. About half of States reported that they pay the provider's actual acquisition cost for the 340B drug plus a dispensing fee, typically, I think, $2.50 per drug, and that's the policy in half of the States. The other half of the States, it might, you know, I assume it's variable, but I'd have to go back and look at the report.

MR. GRADISON: Well, maybe it is relevant. It's something to think about, because that's a similar -- I wasn't actually thinking of 340B, because at that time, that didn't exist, but thank you.

MS. BUTO: So, I have three clarifying questions, one of them to do with 340B, which is how the coinsurance is calculated. Is it calculated based on the Part B rate or based on the 340B rate? In other words, is the beneficiary kind of getting the worst of both worlds? They get the drug, but they're paying the higher copay?

MR. ZABINSKI: It's based on the outpatient PPS rate, not the 340B payment amount.

MS. BUTO: Okay. And, then, the two other questions have to do with the ASP analysis. How did we determine budget neutrality? Did you look at -- was it just looking at all the prices, or was it looking at the weighted average weighted by volume, or how did you come up with budget neutrality when you did that?

MS. NEUMAN: So, we assumed, first of all, current utilization levels, and we estimated total spending under current prices, and then we simulated what the payments would have been. Oh, we set the payment rate such that the payments under Option 1 or Option 2, when you applied them to all the utilization, would get you to the exact same number --

MS. BUTO: The same number. Okay.

MS. NEUMAN: Yeah.

MS. BUTO: Okay. Great. And, then, on Table 3, page 11, you don't break out the mix of drugs in the OPD, and I don't know if that's because we didn't have those or do we -- they look like, just judging by the impact, they're going to be heavily oncology and a couple of others, but I

didn't -- couldn't tell.

MS. NEUMAN: So, the way we broke out the physician was by the physician's specialty, rather than by the type of drug. And, so, we weren't able to do that in that way under the HOPD. That said, there might be ways to get a window into sort of what are the components of the HOPD spending.

A second point is that under the HOPD, drugs that cost less than $90 are packaged, and so we have drugs that are more than $90, and so you're not -- you don't get as much of an increase, and that's why you'll see a little bit of a decrease in HOPD, as well.

MS. BUTO: Okay. I just think it's helpful, if we're looking at the impact of these different options, to know, you know, particularly if certain specialties are hard hit. Is that being done on the OPD? Is there -- are they not? So we have just a sense of the real impact on access.

DR. CROSSON: Yeah. I have two questions. Actually, on this slide, on Part B, could you just clarify what the word "suppliers" mean? Is that the same as wholesalers?

MS. NEUMAN: Suppliers here are inhalation drug

companies that supply nebulizer drugs and also pharmacies that supply oral anticancer oral antiemetics, and immunosuppressant drugs.

DR. CROSSON: Okay. All right. Thank you.

The second question is on the 340B discussion. As I understand it, a hospital, or an entity, I guess, has to qualify to be a covered entity, and one of the parts in the text describes the fact that not only has the number of covered entities increased a lot in the last decade or so, but the number of sites have increased. So, my question has to do with whether we know what the rule is, and that is if a site, or if a covered entity affiliates with another entity, becomes an affiliated site, does that affiliated site also have to pass the rules requiring a covered entity, or is it sort of automatically deemed to be a covered entity because it's affiliated with the first covered entity?

MR. WINTER: So, by affiliation, this example you're thinking of where two, let's say, hospitals merge and become a single organization that files one cost report, or --

DR. CROSSON: No, I'm talking about --

MR. WINTER: -- like a system?

DR. CROSSON: -- what we see increasingly, which is XYZ Hospital, an affiliate of someone else.

MR. WINTER: My understanding from HRSA is that if a hospital files its own cost report, then it's considered a unique organization and it has to apply to HRSA to be part of the program and meet all the criteria. So, it cannot just sort of go along with -- come under the wings of the parent entity. Each individual hospital, if it files its own cost report, is considered a unique entity and has to qualify independently for the program.

DR. CROSSON: So, in other words, when we talk about affiliated sites, the affiliation is not relevant. Each site is a covered entity, qualifies as --

MR. WINTER: So, an affiliated site would be if a hospital has three or four satellite clinics that are included in that hospital's cost report but are listed as separately reimbursable sites, then they are part of that -- they would be considered affiliated sites of that entity --

DR. CROSSON: Right, but if hospitals --

MR. WINTER: -- that entity and hospital.

DR. CROSSON: If Hospital B markets itself as an affiliate of Hospital A, or Hospital A, System A, it doesn't

get a pass. It has to be a covered entity, as well.

MR. WINTER: It has to be -- yes, assuming its own cost report.

DR. MILLER: If it files its own cost report.

MR. HACKBARTH: Well, so that would create an incentive for a single consolidated cost report across all of the affiliates. Are there any restrictions on their ability to do that?

MR. WINTER: I'm not aware that there are any in the 340B program. If there are -- if CMS has rules about hospitals creating a consolidated cost report, that's -- I don't know.

MR. HACKBARTH: Okay.

MR. WINTER: But, if there are CMS rules, those would apply. But, as far as I know, there are no rules within the 340B program of hospitals consolidating, and if they submit a single cost report, then they can be a single entity in the program.

DR. MILLER: The other thing, just to stay on this point for a second, because you may be asking these questions as to how far you can kind of extend your reach. Yes or no?

DR. CROSSON: Yes.

DR. MILLER: Okay. If yes, remember, there's also another overlay here -- and I'm about to get into things that you know better than me -- there's contract pharmacies, and so you can be an entity and then have your own pharmacy, but then you can also contract for other pharmacies which also extend your reach a bit. Now, that's not an entity, but you can -- you have greater reach, and to the extent that that script, that patient has crossed into your threshold, you may -- into your hospital as an outpatient, you may be able to claim a 340B discount that way.

DR. CROSSON: I mean, I guess behind the question is the question of whether the increase in usage of 340B drugs and the costs tripling or whatever it was in the paper means that there are more entities and more drug delivery that meet the original intention of the creation of the 340B program, or, in fact, through whatever mechanism, which is affiliation or consolidation of cost reporting or whatever, the program has now been extended in such a way that it no longer meets the original -- part of it no longer meets the original goal.

DR. MILLER: So, do you want me to go first or

you? You look like you're ready to say something there.

MR. WINTER: No.

DR. MILLER: No, seriously. I'll give you the floor if you want to go first. I know what I would say.

[Laughter.]

MR. WINTER: Now I'm on the spot. If I say something different, I'm in trouble.

[Laughter.]

MR. WINTER: So, there has been growth in the number of covered entities. But, in terms of hospitals, hospital covered entities, that growth has slowed down, and since 2010, much of that growth has been in Critical Access Hospitals and rural referral centers and other kinds of hospitals that were added to the program by PPACA in 2010. There's not been a lot of growth in 340B DSH hospitals, which were the only kind of hospital permitted before 2010. The number of those hospitals in the program have been pretty stable. But, we've seen, still, pretty rapid growth in Medicare spending on Part B drugs at 340B hospitals, and most of those are going to be DSH. Very little of that is going to be for CAHs.

So, the picture I'm drawing for you is that the

number of covered entity hospitals in 340B has been -- it's grown. It's grown 57 percent since 2010, between 2010 and 2014, but there's also been -- but, the number of DSH hospitals has been pretty stable, and Medicare Part B spending -- Medicare Part B drug spending at those hospitals is still rising pretty rapidly.

And, I don't know if that's what Mark was going to say or not.

DR. MILLER: Yeah, it was. You actually, as always, said it better. There was some expansion of entities in PPACA, but the growth rates on the hospital, which is where a lot of the money is being kind of driven through, has been more leveled off, and they're CAHs, but we're sort of talking about them separately. And, then you see this growth in the expenditures.

And, this kind of gets into what sort of he said, she said, and a bit of what we talked about in November. So, some of the drug manufacturers are arguing that the entities are extending their reach through these contract pharmacies, and the hospitals are arguing strenuously, no, we're very careful about establishing that relationship with the patient before we claim the 340B, and they're arguing,

and we use these dollars for very good purposes. And, that's kind of the crux of the argument, why people are even talking about 340B to begin with.

So, it's a bit of both. There have been entity expansions, but then there's been this other growth which, you know --

MR. HACKBARTH: I think it's also important to remember here that 340B is not a Medicare program, and as we emphasized when we discussed this in November, our intent was not to make recommendations on the 340B program. We were just trying to understand it and help others who follow our work understand it. So our focus in this area will be on Medicare payment policy, and these are more questions of how 340B works and how it's managed, beyond the realm of our recommendations.

DR. CROSSON: But my question was essentially to try to understand the dynamics in the 340B program, to then try to understand the degree to which the Medicare program is overpaying, or paying more than it should otherwise be paying.

MR. HACKBARTH: Okay. I have the feeling that we've already entered into Round 2, but let's officially

ring the bell and start Round 2.

DR. COOMBS: Thank you very much. So one of the things that I've thought about is, looking on the Table 3 in the reading material, the differentials between a physician versus hospital outpatient department. And I know this is not the scope of our discussion, but I'm thinking big picture in terms of what actually happens in the physician office in terms of total cost for administration of a drug and the total cost in the OPPS and what kind of data exists for which does it better, I mean in terms of looking at is there anything out there that shows that the benchmarks of quality is better administered in a physician office versus a hospital? Because there's differentiation in cost, and that doesn't mean that there's quality that goes with one provider being paid more than the other.

So, for instance, the administration of IVIG in the doctor's office versus a hospital and the incurred cost that occurs because it's in the hospital with facility charges. Does it justify or warrant the total costs of that drug delivery being in one venue versus the other? So I'm thinking big picture, so it's a lot more than the 60 cents to whatever. And you did a nice job, a really nice job of

doing the distribution of cost in terms of what percentage of drugs are under $50 versus when you get up to the very expensive drugs. So I'm just thinking along those lines.

And then the cost correlated with physician purchase of practices by hospitals, and has there been any kind of correlation with that in terms of the costs.

And then, lastly, I recently had an experience with using a medication, an intravenous medication, which should never be used in the OPPS is diisopropylphenol, without saying the generic name, which is manufactured now in Sweden as a generic -- as a brand, and then in many different places all over the world as a generic. And it turns out the fraction of cost is, you know, a hundred-fold different based on where the drug is manufactured, but also the bioavailability of the drug is considerably different and also what's put in for preservatives.

So I think the hospitals have an incentive because of their margins of where they are in terms of, you know, what we discussed already. There's an incentive to seek out a cheaper product, not necessarily equivalent, but they will have an advantage in the big run if they're able to do a couple of these things such as, you know, prompt payment

discounts in addition to 340B. I think that, you know, looking into that aspect, it makes me think that this should be something -- I don't know what can be done, but the differential that occurs between hospitals and physician offices. And I didn't see that there's any kind of quality information that goes one venue being different than the other.

DR. MILLER: So I heard a couple [off microphone].

MR. HACKBARTH: Your microphone.

DR. MILLER: Although given the value of what I'm going to be able to answer here, it might be better just to leave it off.

So I heard potentially a couple of questions in there, and I'm going to start with what I think was the second one: What is known about the purchase of practices? And there are people out making the argument that part of what's fueling the purchase of practices, and particularly oncology, is the 340B; that the hospital knows that if they can purchase the oncology practice and get 340B, there's an additional revenue boost in there. And there are people who are making that argument.

There's not a lot of evidence on this, but we

looked at some expenditure trends, 340 -- yeah, can you tell her that part? You know what I'm referring to, right?

MR. WINTER: Yeah.

DR. MILLER: It's not a complete surprise.

MR. WINTER: Yeah, so chemotherapy spending has been growing much faster among 340B hospitals than non-340B hospitals, and there was a text box about that in our November paper, and it will be hopefully in our upcoming chapter. I don't remember the percentages, but it was definitely growing faster in 340B hospitals.

Oh, Dan has the percentages, so he'll tell you that in a second.

And so it could be because they are just doing more things within their existing outpatient departments, or it could be because, as Mark was suggesting, they're purchasing community oncology practices and integrating them into the hospital and, therefore, they can use 340B drugs in those practices once they become part of the hospital. And Dan will tell you the percentages.

DR. ZABINSKI: The percentages, 19 percent per year 340B and about 14.5 not 340B. Now, that's pretty healthy in both sectors, but obviously much faster in the

340B.

DR. MILLER: So you do see this phenomenon in both types of hospitals, and as we've presented in other conversations, there does seem to be a lot of purchasing and shifting even beyond the whole oncology question. It's also no surprise that Dan remembered the percentages, just so you --he always remembers them.

The other thing that I would say is then you were asking a question about differential and quality, and I don't think we know much about quality differences between the settings, not in any of our conversations or any data that I'm aware of. And so at least on that point, I don't think there's much we can bring to the table. Is that getting at least into the territory? All right.

DR. BAICKER: So, first, I have to express my great appreciation for your willingness to produce answers to two significant digits to my question about the difference between two imaginary numbers.

[Laughter.]

DR. BAICKER: This is much appreciated, and I'm referring to Slide 16. To me it's really informative knowing all the caveats and the bounding exercise you had to

go through to see the share of revenues that this comprises gives a really helpful sense of the magnitude of the potential incentive at play, both for acquisition behavior, for prescribing behavior. This makes it seem quite salient to me, so I really appreciate those efforts.

Going back to the 106 percent versus the alternatives that you mentioned, I thought it was important to understand from what you've said that there doesn't seem to be any evidence that the cost of storage or anything else that's supposed to be lumped in there varies as a percentage of the cost of the drug, and having some extra flavor of, well, these really expensive drugs also require this really special storage facility or something like that would be a justification. I didn't get that sense from what you had said. So then it goes back to the spread of what people actually pay around this average ASP. And Glenn's clarifying question gave me the answer to the clarifying question, could you actually just produce the spread so we know what share of people are really -- what share of entities or spending would be between 100 and 2.5 and 100 and 6, and thus suddenly go from being in the black to being in the red by one of those revisions, the answer seems to be

no, you can't produce that whole distribution if from secondary data sources or other people's analysis it was possible to have more of a flavor of the spread without the whole distribution. But just to know how big a hit are the bulk -- how big a hit or how big a share the entity is likely to take if we move from one model to the other, understanding it is not going to be precise, but it would help me know how much weight to put on the argument that you need this buffer because the spread of prices is so great that a bunch of entities wouldn't actually be able to get the drugs they need if we brought down that cushion.

MR. HACKBARTH: Round 2?

DR. HOADLEY: So, actually, Kate, that was, I thought, a useful thing. I think you go to one of the right points that we don't really understand, sort of the purchasing variability, there's a lot of anecdotes, and maybe there's a way to get some sense in the industry of where that falls.

I actually thought that the options looked pretty interesting here. I'm talking now about the 106 percent ASP. And I've talked in the past about, you know, one could lower it to 103, just assume that 6 percent is too much, the

notion of going to a flat -- and I thought it was a pretty creative option to sort of go to this hybrid thing, because it is interesting when you look at the low-cost drugs, there's a lot of money on top of a $10 drug when you're throwing that $24 add-on to it. And so I found the hybrid option, I'll call it -- Option 2, I guess, the way you numbered it -- to be -- I think you could actually think of some other variants on that theme. You could think of a flat amount that goes in a couple of tiers at some price levels. Or you could think about some way you blend from, you know, flat at the high end to something. I mean, I think, you know, it's probably not that useful to sort of go down those kind of little details, but I think some notion of this is pretty useful, so I'd like to see us keep thinking about that. I think there's a promising -- and then, you know, you label this as budget neutral without any behavioral impact, and presumably what you -- what a lot of people think you might get is some fairly significant impact on shifting to lower-cost drugs. And CBO has scored some options around this territory of stuff with some savings, so there's presumably actually if you figure that in, there's some potential for savings even starting from sort of this

framework. So I thought that was really helpful.

One question I have in terms of how this is getting presented is are we thinking that this is going to be written in conjunction with some of the least costly alternative and some of the other things we talked about earlier in the year? Or have they sort of gone on separate tracks at this point?

DR. MILLER: I would defer to Jim on this, who keeps track of all of this. I thought the thought was that this ASP and some of this might be its own thing, and then the LCA would be its other own thing. That will look good on the transcript, I'm sure.

[Laughter.]

DR. MILLER: That was the thinking at the moment.

DR. MATHEWS: Yeah, that's correct. Our tentative working plan is we would have a purely informational chapter on the mechanics of 340B. We would have a second chapter that would deal with Part B drug pricing issues. And then there would be a third chapter that would deal with LCA and related policies, and we'll come back to that at the April meeting.

DR. HOADLEY: And at some point when we're -- when

or if we get to talking about recommendations, that might be the point to think about them again more in parallel, because they are to some degree -- there's some ability to make tradeoffs across those, but it seems like a good plan for here.

I also wanted to say on the 340B side, I mean, apart from all these bigger issues, the sort of core of this for us is, you know, where should Medicare be? And it does seem like -- and I'm not yet clear where we ought to end up if we were at some point in the future going to make recommendations about a Medicare pay policy, but you could think about things like the way Medicaid does it with the average acquisition price -- or actual acquisition price, so, you know, you say it's ASP, but if you're in the 340B world, you don't get that, you get what it cost you plus an add-on of however that might be calculated, which would in a sense be -- another way to sort of think about that or label that would be almost like creating a separate ASP for the 340B world to the extent that they're all kind of paying the same thing, maybe there's not really an averaging concept in there.

MR. HACKBARTH: It gets tricky, though, doesn't

it? You know, you could say, well, we're just approaching it as a Medicare issue. But to the extent that you reduce Medicare prices to match 340B acquisition costs, you're frustrating the intent of 340B.

DR. HOADLEY: And that's why I say I'm not sure -- you know, I'm not sure where to go with that. It seems like that's the option --

MR. HACKBARTH: Right.

DR. HOADLEY: -- we could sort of put out there as the thing to then think about pros and cons, and that's one of the cons.

MR. HACKBARTH: Right.

DR. HOADLEY: So maybe it's, you know, some percentage of --

MR. HACKBARTH: Yeah.

DR. HOADLEY: Maybe it's 110 percent of those 340B prices, so you do part of that.

MR. HACKBARTH: So I'm thinking about this on two levels. You know, one is what would be a good policy, and what you're describing may be one approach to that. But then the second level is just the jurisdictional level. To what extent do we want to start making recommendations that

start to undermine the effect of a Public Health Service Act program? Is that just a good place for us to be in terms of what MedPAC's role is as an adviser to the Congress? Those are questions, not answers.

DR. HOADLEY: I think those are good questions, and part of that is whether -- I mean, the argument often gets made that the savings from 340B is supposed to go do something. Another argument for 340B is it's just for the kinds of institutions that are serving low-income populations, we want to make a more discounted price available. So if you sort of go off that logic, then saying, well, Medicare profits by that is a reasonable way to do it. But if you're more in the first logic, then you've got the undermining things. So I think that sort of to me captures the two -- at least two of the potential arguments around that.

MR. HACKBARTH: And one of my takeaways from our November discussion was that, you know, exactly what the purpose was and how this was supposed to work and who was supposed to benefit, it's pretty murky, which is one of the problems. You know, exactly what is the policy objective here? It's a program that has been run rather loosely, I

think. I don't know. Again, those are just questions. I'm not sure where it will end up here.

So we're on Round 2.

DR. HALL: [off microphone] huge amount, and I guess there are kind of three unknowns that I took away from this. I'd just like to sort of frame whether -- at least one area where we might be able to do something productively very quickly.

So we know the 6 percent surcharge is murky in terms of its justification, and, therefore, anything we do to fool with it, making it 2 percent or 3 percent, may still not be looking at the root cause of why we're doing it in the first place and what this money is really being spent for. And maybe it is and maybe it isn't. Maybe it's too low.

The second thing is that I found there were so many exceptions to pricing, whether it has to do with the ASP, with the 340B, with discounts, with rewards for paying on time or paying early. So it may be -- we've probably got the data right, but there are so many other parts that come into this that kind of bother me.

And then there is the presumption that there may

be some gaming of the system, and that may be or it may not be.

So one of the things that I was left with is that on Table 1 in the materials that you sent us before -- I think it was referred to already -- we compare the percentage of all Part B drug administrations and the percent of drugs furnished per beneficiary per day versus the drug payments. It's the same rule we've seen almost everywhere along the way. So, I mean, where I made a cut on that is if you're paying more -- at least $1,000 for a drug, that puts it, I think, into a high-priced drug. And if we look at all those drugs where you pay $1,000 per dose up to greater than $5,000 a dose, that's about 12 percent of all the drugs that are administered in Part B. So now we're narrowing this down to a very expensive cohort because that happens to represent 80 percent of the entire cost of all Medicare -- of Part B drug administrations.

Now, where the hooker comes in on this -- and I'll be brief -- these costs may be bad or they may be good, and it's the first time in history that we've had drugs that really work. The biologics and, I would argue, some of the newer antibiotics have made a huge increase in the quality

of life for Medicare recipients. So we fool with this at our peril, because if we're trying to incentivize people to use aspirin instead of a specific drug for your lymphoma, we're not -- we're cutting costs -- and that's a stupid analogy. But we're not really getting at the problem.

So I wonder if a little more of a deep dive on those drugs, let's say arbitrarily $1,000 and more, to learn a little bit more about them and what are the opportunities, if there are opportunities, to maybe put a little more rationale, because that's also where the 6 percent add-on is really adding to almost the entire cost that we're worried about. But I don't really know what's in that category, but I think we've mentioned some of the things that are probably in there.

So if we want to reduce costs in a rational way, that might help us to come up with something that would be very useful for policymakers.

MR. HACKBARTH: Those are good points, Bill, and I'm way out of my depth here in talking about these issues. But just as a reader of the newspaper, I've seen stories about cases where there are multiple drugs, vastly different prices attached to those drugs, and from a clinical

standpoint at best, small incremental gains, if any, associated with a much more expensive drug, yet we see physicians prescribing the most expensive drug. And it makes me wonder to what extent is that linked to this.

DR. HALL: That's another unknown.

MR. HACKBARTH: Yes.

Has anybody studied that? Is there any academic research on that?

DR. HOADLEY: I'm not sure if there is research on sort of directly getting to the incentive that are used to do it, but certainly, the eye drugs, Lucentis and Avastin, have been illustrated multiple times by the IG or GAO in terms of just the dollar effect. The question of what's the behavioral or what is the financial incentive, I mean, it seems obvious, but to sort of demonstrate it at the more behavioral level, I'm not sure anybody has tried to necessarily do that.

I guess you guys mentioned the one example in the literature, but otherwise, you're saying there isn't much literature. I think that I would agree with that.

MS. BUTO: Yes. On the point you raised, Glenn, about whether Medicare policies should undermine the public

health service, 340B program, I think the original rationale for 340B pricing was that drugs should be provided at a low price to those facilities because of the situation that they are in.

I don't know that there was an overt intent to then, in addition, subsidize the operating costs of 340B hospitals and other entities with the spread, if you will, between what Medicare reimburses and what they actually then pay for. So I would just question that.

We at least ought to acknowledge that that is there. I don't know that we have a solution per se, but I think it is worth mentioning, and it still bothers me, the beneficiaries are paying their copay based on the Medicare rate, not on what essentially is the Medicaid rate for these drugs.

MR. HACKBARTH: Help me out here. My recollection from our November discussion is that the proponents of an expansive 340B program have some specific language that they point to, to suggest that, "Oh, yes. The objective was to allow these institutions to get the additional margin in order to advance their safety-net sort of goals."

MR. WINTER: I can read that for you, if you want.

DR. NERENZ: It is in our materials, at least the --

MR. HACKBARTH: Would you read it?

Ariel has it right there.

DR. NERENZ: Yes.

MR. WINTER: It is on page 13 of your mailing paper from this month.

The conference report that accompanied the legislation said that the program's intent is to enable covered entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. There is other language in the conference report, which strongly implies that the intent of the program is to help entities that are serving low-income or uninsured patients.

MS. BUTO: Right.

I guess I could read that to say that the stretched, scarce resources can be better made available if they can purchase drugs at a very low rate. In other words, it frees up their other operating costs. Anyway, I don't want to argue about it. I just think we need to highlight that and the coinsurance issue.

The other thing I know we talked about a while ago was this idea of episode-based payments, and I saw that CMS has just started a demonstration, and it is more along the ACO model, from what I can tell. In other words, entities get paid, fee-for-service, and then there is some reconciliation against a target. I wonder whether we ought to, in this section, mention that as another alternative that we have talked about because that one includes a much more bundled -- includes hospitalization and other services, not just the drug and the physician administration.

I think that, ultimately, for some of these really expensive drugs, that more bundled approach might be a more appropriate way to go, particularly if the drug costs take into account all of the alternatives that are available, not just the most expensive one.

MR. HACKBARTH: Thanks for raising that, Kathy. I think that's a really important point.

Off the top of my head, I can't think of any other part of the Medicare program that uses a payment method like this. Can you --

MS. BUTO: Like ASP-plus 6 percent?

MR. HACKBARTH: Yes. I think this is --

MS. BUTO: Well, you could sort of say this about everything. I can't think of any other part of the program that uses DRGs or OPPS or SNF payments.

MR. HACKBARTH: Yes.

MS. BUTO: I'm not sure what you're getting at there.

MR. HACKBARTH: Well, what I am getting at is where you have at least this risk, and we're not sure how big the risk is because we don't know anything about the distribution of acquisition cost, but at least this risk, where you have a payment methodology that very directly could encourage a provider to substitute a high-cost item for a lower-cost one, that it basically produces money that falls right into their bottom line.

MS. BUTO: I can't remember, but there are a number of fee schedules that reward, don't just pay at sort of an average rate, and so I can't speak -- I haven't seen them lately, but that might induce higher utilization. In fact, I think the SNF example we use is because therapy services can be added on to a visit, there is an inducement to use more of them.

MR. HACKBARTH: Well, there's certainly payment

systems --

MS. BUTO: Yes.

MR. HACKBARTH: -- an army of them that create an incentive for higher utilization, and because payment rates and prospective systems are based on average -- there can be larger gains there, but it's by reducing cost that you increase your gain.

Here, the gain is you win by not increasing the number of units. Units are constant to substituting a higher cost input, and I can't think of other payment --

MS. BUTO: I wouldn't use the word "cost," necessarily. In other words, the best position to be in is to choose a high-cost drug but get a low-cost on that high-cost drug --

MR. HACKBARTH: Yes. And here I am using cost --

MS. BUTO: -- to get the reimbursement.

MR. HACKBARTH: -- as cost of the Medicare program as opposed to acquisition cost of the project.

MS. BUTO: Right.

Well, the same is true in the DRG system. The best position to be in is to be able to provide and deliver that bundle of services for a given DRG, using lower cost

inputs than were actually accounted in putting the rate together. So it is the same concept, but anyway, that was my point about the episode-based payment. I think that is another whole --

MR. HACKBARTH: In fact, that is where we agree --

MS. BUTO: Yes.

MR. HACKBARTH: -- is that by looking particularly at some of these high-cost drugs, many of which -- not all of them, by any stretch, but many of which are oncology drugs, and using different methods of payment, I think may be a more productive course than thinking about should it be 106 percent or 103 percent. I think that is where we're lined up.

DR. MILLER: Can I --

MR. HACKBARTH: Yes.

DR. MILLER: You asked if there are other places in Medicaid where it works like this, and I don't have examples of that.

When you think about it, this problem is handled differently in different types of settings. So in a lot of the PPS's, like, say, in patient PPS, if you have a risk, you run some loss and then outliers come in and kick behind

you, and then if you do well, you profit from it.

There's corridors in D. There are different ways this risk tries to manage the provider, but you're right. I'm not sure there is one quite like this. We can go back and think about it, but this problem crops up in the payment systems. It has just been dealt with in different ways.

MR. HACKBARTH: We need to finish up Round 2. Herb, Jay, and Scott.

MR. KUHN: Just a comment or two about the 340B program and picking up a little bit where Kathy was talking about, this notion of stretching scarce federal resources across the way, the way I have always looked at it is that it's almost like a supplemental or an add-on payment for this class of health care providers, kind of like DSH, kind of like GME, some of the other add-on payments that are out there.

So I think Glenn is right. This is really a HRSA program that has been developed to provide an add-on payment for this set of services that are out there. It never was designed as a program for the insurers to be able to get rewards out of it or get additional discount. It was the way to make a supplemental payment through this discount to

these other class of providers.

So I think if we think about policy issues into the future on that, we would have to go back, I think, to some of the things Glenn has talked about in the past. How do you target payments? Where do you target them? Is this the best way to target, or is there another way to do it? And it's just to have to think through in the future.

DR. CROSSON: I will be quick because I am going to reiterate some stuff that has been said.

We started out in this thing kind of reflexively. Gee, 106 percent across the board. That is likely to create an incentive for providers to use more expensive drugs. It seems logical. Therefore, let's see if we can't find some other mechanism of payment, which at least narrows that.

As Jack, the one that attracted me the most was option 2, because it seems to do it in a moderate way, by creating incentives, perhaps, to use less expensive drugs.

I've got a problem, though, and I think it's similar to Bill's, and that is that I don't think we -- and this all comes in the category of we need more work. I don't think we actually have evidence in front of us that what we think might be an adverse incentive actually is, for

some of the reasons that were discussed. I'm not sure how to do that.

I think Lucentis and Avastin aside, one way might be to take five or six of the most commonly used or most expensive drugs or some combination and try to actually study the utilization, perhaps through interviews, if that's possible, because I'd feel more comfortable saying let's upset the apple cart and get rid of the 106 percent if I was confident that we were actually solving a problem that really exists or as opposed to just might exist.

Then the other question about trying to understand whether the real de facto justification for the 106 percent is the variation in acquisition costs -- I've had some anecdotal comments by, particularly, oncologists around that -- because if that is in fact the case and we move down the recommended direction, even option No. 2, what we may find that we've done is to put a financial burden on smaller practices, for example, who are having trouble making it with the 6 percent and couldn't make it with some other combination.

It might be -- I realize that with respect to the manufacturers, we are not going to get that information, but

is it not possible to find out, for example, by interviewing a set of oncologists or other physicians, what their actual spreads are? I realize we'd have to believe that we could trust the information we are getting, but I don't think --

I see some shaking of heads already.

But I do think that it might be possible on the provider side to find out what in fact the experience is and what the punitive spread it, at any rate.

So those are two comments of annoying work.

And my only other comment on 340B is that everything that's been said about jurisdictional issues, I understand and agree with. However -- and I think Kathy said this. Is the key issue here perhaps -- and perhaps one that is accessible -- the question of whether Medicare beneficiaries should be paying more than they otherwise would fairly be paying based on their expectation of what the percentage is that they are supposed to be paying, and isn't that in fact a legitimate issue for the Commission?

MR. HACKBARTH: Scott.

MR. ARMSTRONG: [Shakes heads no.]

MR. HACKBARTH: Okay. Jack, go ahead.

DR. HOADLEY: On that list point or the next to

last point that Jay made, I wonder if this is something CMS is allowed to do with the data they collect to calculate ASP to actually look at distributions and whether that's something either that they could be asked to do or whether they could just do to get to this point of how much spread there is around, because they have the data that went in to calculate the ASP. They are not allowed to make it available to others, but presumably, they can do some math on it. I don't know.

MS. NEUMAN: So the manufacturers report the data at the aggregate level. They don't report it at the transaction level. So they don't have the variation.

The only folks who have done this kind of thing, I would say, is the OIG, and they have tended to focus on the average, but they have probably the most capacity, I would imagine, of anyone to compel production of that --

DR. HOADLEY: Because they can compel the particular data.

DR. MILLER: And if we could identify the variation -- and I was taking notes -- I thought your third comment was about do we understand the variation of the 106, but then is that about the spread, or is that about storage?

I think even if you knew the variation, would you know the answer to whether the dollar is just a purchase -- well, I guess if you really knew the purchase price, you would. Okay. I take it back. I withdraw.

MR. HACKBARTH: Davie, last word.

DR. NERENZ: Yes. Just very quickly, a quick reaction to what Herb and Jay said.

I think I share Herb's view of the way at least I read this language. I understand people can read congressional language in different ways, but it does not say that it is just about passing or making drugs more readily available, and it explicitly does not say to reduce Medicare expenditures. I have read it the same way.

In terms of Jay's point about paying, beneficiaries paying more than they otherwise would, I am not sure that I think that phrasing is quite right because if 340B was just flat eliminated tomorrow, the cost of Medicare payments would not go down. Beneficiary payments would not go down. Nothing would change. It does not change what Medicare pays, nor does it change what beneficiaries pay. The only reason that the concept of "would otherwise pay" is if you assume some downward

matching tracking in the Medicare program.

The 340B itself does not raise Medicare payments nor beneficiary payments for these drugs, as I understand it.

DR. CROSSON: I guess what I was thinking -- perhaps I'm incorrect here -- was that the expectation is, in terms of out-of-pocket payments of beneficiaries, that they are paying some percentage, and in fact, they're paying a greater percentage of what it costs. Am I off somewhere here?

MR. HACKBARTH: They pay a percentage of the Medicare payment.

DR. CROSSON: Right.

MR. HACKBARTH: That is the statute. They don't pay a percentage of the cost; they pay a percentage of the payment.

DR. CROSSON: All right. So then I'm wrong.

So their only expectation is to pay a percentage of what Medicare pays.

DR. COOMBS: Isn't the argument as well that you're doing critical access hospitals and you're doing DHS, that many of them are LIS? And I don't know what

percentage, but you would assume that there is a large population of the last there as well, low-income subsidies. Would that come into vogue as well?

MR. HACKBARTH: Well, that's Part D.

DR. COOMBS: Okay.

MR. HACKBARTH: That doesn't affect Part D cost sharing for Medicare.

MR. KUHN: At least for a lot of those organizations because they're high-DSH hospitals. It is a proxy for those lower income Medicare beneficiaries.

DR. MILLER: Which that --

DR. HOADLEY: There would be more duals that would have their costs picked up by the states. That's true.

DR. MILLER: Which don't pay the copayment. Right.

DR. HOADLEY: Right. I mean, the point is you can make the case that if the hospital is getting it at this lower cost, that the Medicare beneficiary who is eligible for the copay could get it at that, 20 percent of that lower cost that they incurred as opposed to the Medicare payment. I think that is where your point goes.

DR. MILLER: Right. And that is what I was going

to say. I think both statements are correct. It is correct that if 340B didn't exist, the beneficiary would be paying 20 percent of the Medicare rate.

It's also a question that if the rate is actually less, should the beneficiary see some benefit from that? I don't think your statement is wrong. I think it is more of a question.

MR. HACKBARTH: And it just brings you back again to the question: Is it an appropriate thing for MedPAC to do to recommend a Medicare payment policy change that may frustrate the intent of the 340B program? Hey, I'm not going to be around until you folks can figure out the answer to that question on your own, but that's something I think you need to think about.

Okay. Thank you very much, Kim and Ariel and Dan, obviously an engaging issue.

And so let's move on to our last session for today on synchronizing Medicare policy across payment models.

[Pause.]

DR. MILLER: Okay, Julie. Do it.

DR. LEE: Good afternoon. In the past couple of years, the Commission has been thinking about the

relationship between different payment models under Medicare, such as ACOs, Medicare Advantage, and traditional fee-for-service. Last year, we began our discussion on synchronizing Medicare policy across the payment models.

So, let's begin with a review of previous presentations. Under the current Medicare program, there are three payment models: Traditional fee-for-service, MA, and ACOs. The payment rules are different and inconsistent across those models, and as a result, program payments can be quite different for similar beneficiaries across the three models.

In January's presentation, we showed that no one model is uniformly less costly to the program in all markets. Overall, our discussions so far focused on equalizing spending benchmarks across the payment models.

In today's presentation, we shift our focus to the beneficiary perspective. First, we begin with a brief review of what the three payment models look like for the beneficiary and the broad policy context in which to think about their perspective. Next, we'll outline our framework for analyzing beneficiary premiums associated with the different options for Medicare coverage. We'll describe two

specific market areas we'll use throughout our presentation, then go through three illustrative examples for calculating beneficiary premiums. And, finally, we'll end with several caveats to our analysis.

Under current law, traditional fee-for-service, ACOs, and MA are not three distinct models from the beneficiary perspective. Traditional fee-for-service and ACOs look essentially the same. Under both models, beneficiaries get the same Medicare benefit package and pay the same Part B premium and they're attributed to ACOs. They don't enroll. Although ACO providers can encourage beneficiaries to stay within the ACO, there are no rules stopping them from going to other providers outside the ACO.

By contrast, beneficiaries' experience in MA is very different. First, they may get different benefits compared to what the fee-for-service and extra benefits if their plan spend is less than the MA benchmark. Second, they must enroll in an MA plan. And, third, MA plans generally have a limited network of providers.

Here's a broad policy context for today's discussion. Much of the Commission's work focuses on creating incentives for providers and private plans to

improve the quality and efficiency of the program, but beneficiaries also have a role in those efforts. In particular, we want to explore ways to create financial incentives for beneficiaries to choose efficient models. If we can encourage them to choose the model with the highest value in terms of cost and quality, there are potential savings in program spending that can be shared with the taxpayers and beneficiaries.

The goal of our analysis is to consider beneficiaries' choice between fee-for-service and MA and compare their premiums under different approaches to calculating beneficiary premiums. Our framework has three steps. First, we define a market area that matches the insurance market. We use a definition that's consistent with the Commission's previous recommendation. In urban areas, a market is a set of counties in the same State and the same CBSA. In rural areas, a market is a Health Service Area.

The second step is to calculate average fee-for-service spending at the market level. It's calculated per beneficiary per month and standardized for a beneficiary of average health status.

The third step is to recalculate MA plan bids at the market level. Under current law, each MA plan chooses counties that make up its service area, so we have to make adjustments in converting current MA plan bids to the market level.

A more detailed description of these steps is in the paper, and I'm happy to go over them on question.

So, for simplicity, all of our analysis will be based on fee-for-service spending and MA plan bids at the market area level, calculated per beneficiary per month, and standardized for average health status. We also assume the quality is constant among different options.

Here's a brief description of two market areas, Portland and Miami. We'll be using them throughout the analysis. Portland is a low-spending area with average monthly fee-for-service spending in the low 600s, whereas Miami-Dad is a very high-spending area. Both markets have a large number of Medicare beneficiaries, and both markets also have many MA plans available, and the overall MA enrollment rates are high.

In our analysis, we look at three different ways for calculating beneficiary premiums. Under the first

illustrative example, the base premium is set to a fixed percentage of the national average fee-for-service spending and beneficiaries can buy fee-for-service Medicare in every market at that price of premium. In other words, there's a single national premium that's the same for all markets. This approach is similar to how Medicare currently calculates the Part B premium.

Under the second example, the base premium is still calculated using the national average of fee-for-service spending, same as in the first example, but in this case, beneficiaries can buy at the base premium either fee-for-service Medicare or the referenced MA plan, whichever is lower cost in each market. In other words, if fee-for-service is lower than MA, then the base premium would buy fee-for-service Medicare. But, if fee-for-service is higher than MA, then the base premium would buy the referenced MA plan. Therefore, what people can buy at the base premium will vary across markets depending on how fee-for-service compares with MA.

Under the third example, we change the formula for the base premium. Here, it's set to a fixed percentage of the local average fee-for-service spending, and with that

base premium, beneficiaries can buy either fee-for-service Medicare or the referenced MA plan, whichever is lower cost in each market. In other words, in markets where the local fee-for-service is lower than the national average fee-for-service, then the base premium would go down, whereas in markets where the local fee-for-service is higher than the national average, then the base premium would go up.

For simplicity, let's go through each of the three examples for our two market areas, Portland and Miami. For illustration only, we picked the median MA plan bid as the referenced MA plan, but defining the referenced plan is a policy choice. For instance, it could be the lowest bid, the second-lowest bid, or something else. One final simplifying assumption we make: We assumed that the base premium is set to 13.4 percent of the Medicare Part A and Part B benefit cost.

So, let's look at our first example on this slide, where the nationally set base premium buys the fee-for-service in every market. The base premium is set to $101, or 13.4 percent of the national average fee-for-service spending in our data. You can see this calculation in the middle figure on the slide.

For $101, beneficiaries can buy fee-for-service Medicare in Portland, shown on the left. In Portland, the reference bid, or the median plan bid, is higher than fee-for-service. The difference is marked with a bracket on the top. So, if beneficiaries choose MA, then they would pay a higher premium equal to the base premium plus the difference between MA and fee-for-service. Keep in mind that even though we show only one MA plan here, there's a distribution of other MA plans available in Portland, as we saw in the previous slide. If beneficiaries choose one of them, their premiums would be adjusted accordingly based on their plan bids.

So, to sum up, in Portland, beneficiaries would pay a premium of $101 for fee-for-service and a higher premium for MA. As a result, the government subsidy in Portland is $525.

Now, let's look at Miami on the right. As in Portland, beneficiaries would pay $101 for fee-for-service. But, in Miami, MA is much lower than fee-for-service. So, if beneficiaries choose MA -- so, in Miami, MA is much lower than fee-for-service, so if beneficiaries choose MA, we assumed in this example that they would keep the difference

as a rebate or extra benefits. As a result, the government subsidy in Miami in this example is over $1,000.

So, moving on to the second example, where the nationally set base premium buys either fee-for-service or MA, whichever is lower cost, as in the first example, the national base premium is still $101. In Portland, on the left, fee-for-service is lower than MA, so $101 is the premium for fee-for-service and everything is exactly the same as it was under the first example.

In Miami, on the other hand, things look quite different this time. Because MA is lower than fee-for-service, the base premium of $101 only buys MA and beneficiaries would have to pay the additional $408 in higher premiums if they want fee-for-service. That means the government subsidy has decreased by over $400 in Miami compared to the first example.

So, to sum up, in Miami, beneficiaries would pay the base premium for MA, but they will have to pay a much higher premium for fee-for-service. Holding everything else equal, they will have a strong incentive to choose MA.

Now, let's look at the third and final example, where the base premium is set locally in each market, which

means the base premium in this example is equal to 13.4 percent of local fee-for-service spending, not the national average. Therefore, it's $84 in Portland, whereas $154 in Miami.

As in the previous example, the base premium buys either fee-for-service or MA, whichever is lower cost. So, in Portland, beneficiaries can buy fee-for-service for $84 but pay a higher premium for MA. Since the base premium is lower compared to the second example, the government subsidy is higher.

By contrast, in Miami, beneficiaries can buy MA for $154, but pay a higher premium for fee-for-service, and since the base premium is higher compared to the second example, the government subsidy is lower. Under this example, beneficiaries pay a share of a geographic variation in fee-for-service spending.

Here's a summary of the three illustrative examples we just discussed. The table shows beneficiary premiums for either fee-for-service or MA, whichever option beneficiaries can buy with the base premium. For instance, if you look at the second example in the middle, the base premium of $101 buys fee-for-service in Portland whereas it

buys MA in Miami. If beneficiaries choose other options, then they might have to pay more.

For instance, under the second example again, beneficiaries that pay more for MA in Portland, but they pay more for fee-for-service in Miami. In other words, in some markets, fee-for-service would have higher premiums, whereas in some other markets, MA would have higher premiums.

Under the first example, there are potential savings in program spending only if MA plans underbid fee-for-service and the beneficiary chooses the MA plan. By contrast, under the second and third examples, beneficiaries would have to pay more for either fee-for-service or MA, depending on which option is the higher cost. Therefore, there are potential savings in program spending in all markets.

There are several important caveats to our analysis. First, we assume the quality does not vary across the beneficiaries' choices. This is unrealistic.

Second, for simplicity, we compared just fee-for-service and a single MA plan in each market area. But, as we noted earlier, there's a distribution of MA plans available in many market areas.

Third, our analysis is static in that we haven't modeled how MA plans would bid differently or how beneficiaries will choose differently if rules for calculating beneficiaries change. Our analysis used plan bids from the current MA program, which is different from the three examples we looked at today. 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.

In addition, we haven't discussed how beneficiaries would respond to changes in their premiums. Our examples show that any changes in the method for calculating premiums can have a major effect on their finances, but our analysis didn't address how individual beneficiaries would tradeoff premiums and other aspects of the benefit package as well as their perception of quality of different choices. In some markets, the share of fee-for-service Medicare could be quite small.

Our examples are for illustration and they don't represent a definitive or comprehensive set of design choices. There are many other ways to calculate beneficiary

premiums.

And, finally, there are additional considerations on how to moderate policy impact, such as transition and sharing of potential savings between the program and the beneficiary.

Here are some questions for you to consider.

That concludes our presentation, and we look forward to your discussion.

MR. HACKBARTH: Thank you, Julie. This is really thought provoking for me. Could you put up Slide 7 for a second?

One of the things that really struck me was the median MA plan bid in Portland versus Miami and how small that difference is relative to the difference in fee-for-service costs. And I knew that the difference was smaller. How much smaller it is was really striking to me. I'm not sure exactly what I make of that, but, boy, that really jumped out at me.

Just for the people in the audience, I think Julie touched on this in her intro, but I just want to underline it for the audience. For those who have followed our work on synchronizing payment across different models, usually

we've talked about fee-for-service, ACOs, and Medicare Advantage plans. This analysis, as you just saw, focuses exclusively on fee-for-service versus MA, and the reason for that is that here we're focused on an enrollment type choice that beneficiaries might be asked to make; whereas, ACOs, as you know, beneficiaries are assigned to ACOs. It's not a beneficiary choice, and so it sort of falls out of this analysis.

In our MedPAC conversations about ACOs, we've concluded that, for at least the time being, we think ACOs ought to continue to be an assignment-based system; that is, a non-enrollment model. But ACOs might be authorized to incorporate incentives that would cause beneficiaries to want to use their care delivery system, like lower co-pays for primary care. But ACOs are not part of this analysis because it's a non-enrollment model, unlike MA.

So clarifying questions for Julie? I think we started over here last time. Bill, we'll start with you this time.

DR. HALL: I'll pass on that [off microphone].

MR. GRADISON: I'm looking at page 8 of the paper you sent out in advance, and just an observation. There's a

small number of market areas, 30 in this chart, which less than 4 percent of beneficiaries. That makes me wonder whether in some -- this is the thought that comes to me from that, that focusing on the fee-for-service cost as a basis for much of anything may not be that meaningful because it's such a small part of the market. And I'm mixing terms and I understand what I'm doing here, but it's almost like it's a death spiral in the sense that it's so small that you can't draw any conclusion from it in terms of the other markets.

I don't want to elaborate upon that, but even if you move up to include the two bottom categories, you still have a relatively small -- less than 30 percent of the beneficiaries in those programs. So I guess what I'm really thinking is -- I'm trying to ask myself this question. Does it make sense in markets which are dominated by MA, with very high percentages of people in MA, to focus on the fee-for-service cost? Maybe the whole paper of this is to say no, it isn't, and that you have to look at it market area by market area. But if there's going to be a standard for the whole country and we're going to have -- whether it's high cost or the low cost or the national average based upon fee-for-service, you might get some rather odd results -- and I

think we do here -- because such a small proportion of the beneficiaries are even involved in the fee-for-service anymore, in a few areas.

MR. HACKBARTH: So, Bill, I'm not sure that I'm following. You pointed to Table 1 on page 8, and I think you were focusing on that last row.

MR. GRADISON: Yes [off microphone].

MR. HACKBARTH: Number of market areas, 30; percent of beneficiaries, 3.8. So the way I'm interpreting this table is that there are 30 market areas that have average monthly fee-for-service spending between 900 and 1,151, and they encompass only a little less than 4 percent of beneficiaries.

So are you saying that you think that using Miami, which -- Miami's one of these, right?

DR. LEE: Miami is actually the highest [off microphone].

MR. HACKBARTH: Yeah. Are you saying that because Miami is such an outlier that it's really not a good example for the illustration?

MR. GRADISON: Yes, that's what I'm wondering about. Looking at Table 5 on page 16, I think it's even

more dramatic, because if the -- the amount that you'd have -- the premium you'd have to pay for fee-for-service, if I understand it correctly, in some of these categories on page 16 is sky high. Nobody's going to do that. It would put fee-for-service out of business in Miami, just as -- it's illustrative. I understand that. But using that illustration, I think there would be mighty few people sign up for fee-for-service in Miami. That's all. Okay. Enough said.

MR. HACKBARTH: Yeah. So clarifying questions? Everybody's clear.

DR. COOMBS: I had a question [off microphone].

MR. HACKBARTH: Alice. Or not, right.

DR. COOMBS: So hospice, remind me again, did we include or not include on one side versus -- fee-for-service versus MA?

DR. LEE: Hospice is excluded from both.

DR. COOMBS: From both, okay. Thanks.

MR. HACKBARTH: Other clarifying questions --

DR. MILLER: Just to clarify that a little bit further, that's why our base premium doesn't add up to the -- in part, you know, why it doesn't add up to the base

premium, and the reason that we're having to do that is we're trying to make comparable comparisons between the different fee-for-service and MA. So that's why this is very illustrative in the final analysis.

MR. ARMSTRONG: To Slide 14 under caveats to the analysis, I really appreciated that. Just one additional question I would have would be: There's significant variation in terms of compliance and regulatory costs for Medicare Advantage plans. Did we try to make an adjustment for that? Or would that be another caveat, that we assume that those costs are all the same?

DR. LEE: We did not make any of those type of adjustments. We just took the standardized bid the plans submitted. If those are reflected in the plan bids, then those would be included.

MR. ARMSTRONG: It would just be folded in the cost of -- that would be reported through the bids?

DR. LEE: Yes. So it's what the plans submitted as their bid so that -- as a cost of providing Medicare Part A and Part B benefit.

MR. ARMSTRONG: Okay.

MR. HACKBARTH: Other clarifying questions?

DR. NAYLOR: To build on that, then maybe I don't understand, but -- so you also didn't include in the fee-for-service what it costs to run Medicare program. Is that correct?

DR. LEE: That's correct.

DR. MILLER: This is program spending -- or benefit spending.

MR. HACKBARTH: Any other clarifying questions?

[No response.]

MR. HACKBARTH: Okay. Round 2.

DR. BAICKER: I thought the examples were really helpful and highlighted -- to me the three seem to be getting -- the three options seem to be getting at the same structure, which is the difference in cost between the fee-for-service -- the benchmark and the increment -- let me start again. The difference in cost between a fee-for-service and whatever MA plan would be paid by the beneficiary. So the incentives in each of the three options are the same. If you look at the beneficiary's difference in cost, in premium, for fee-for-service versus the MA example, it's the same delta in each of the three. It's just there's a different fixed premium amount that a person

is paying regardless of which plan. And the question that the three examples highlight is what's that fixed amount? Are you entitled to fee-for-service so the fixed amount should be that and the delta should be above or below that? Are you entitled to the lowest-cost plan that's available so the delta should be added on to that? And does that entitlement vary across areas? If the cost of those services is higher, should that base payment vary across the areas?

And in some sense, the first two options is really just a lump sum that we're deciding -- not that we're choosing one of these options, but that these options make a distinction in the lump sum the beneficiaries would have to pay, and it has nothing to do with which choice; we're just dialing the lump sum up or down. Whereas, the third option adds the layer of who's responsible for the geographic variation. Do we want to inoculate beneficiaries, so to speak, against the variation in the minimum cost of providing care in their area? Or do we think that somehow there's endogenous choice of services that are delivered, and if we had that feed back into the premiums, we might be able to hold the costs down? To me, the reason to have the

premium be higher for beneficiaries in areas of the country where both are ratcheted up would be because we think that feeds back into stemming the overproduction of services.

This is our first discussion of this particular -- I'm still open-minded about this. My suspicion is that that's a pretty indirect mechanism to rein in high-cost areas. So I'm not sure how much it buys us to have the beneficiary premium be higher as a baseline in parts of the country where the expenses are higher. I think the likelihood of that stemming spending growth probably isn't that high, but I'm open to being persuaded otherwise.

And then the question is: Given the delta being the same between MA versus fee-for-service, what do we want that lump sum amount to be? And I'm not clear -- that's just a distributional question -- about how much we think people ought to be paying, and are we worried about people necessarily having access to fee-for-service? Or do we want them to have access -- with no incremental cost? Or do we want them to have access to a plan that we think delivers sufficiently high-quality services? And then anything else is an add-on.

MR. HACKBARTH: Kate, would the academic

literature help us here in terms of whether there would be a different beneficiary response to the first two models?

DR. BAICKER: I think it depends on credit constraints. I can say that it costs you $500 more to have Option B than Option A. That's pretty different if I start you off at zero versus if I start you off at 500. There are two reasons that people might treat that differently. There's the psychology of losses versus gains being incorporated differently, and that asymmetry, prospect, loss aversion, suggests that people really kind of set at the -- wherever you start them off, losing $200 from that, they're much more hesitant to do than gaining $200 from a base that was 200 lower. So there's an asymmetry there. It's probably second order. Probably more serious in my mind would be the credit constraints that you could say, okay, this costs $500 more, and if you're particularly low income, you may not be willing or able to make -- the choices I think would vary more by income when it's all up than when there's money coming into pocket. I don't know, you know, it's not clear to me.

MR. HACKBARTH: You also have the issue of how plans respond, and we talked at one of our recent meetings

how although plans in theory might say, you know, we're going to not just wipe out your Part B premium -- your drug premium, but we'll wipe out your Part B premium and send you a check, but that doesn't seem to be actually how they behave. You know, we had some theories about why they don't behave that way. And the one example, you know, it was -- I forget the exact number. It was the plan might offer a $400 rebate in Miami, but actually they don't seem to be doing that. And why is it that they don't do that?

DR. BAICKER: And did we think there were any regulatory barriers to that?

DR. MILLER: So there's people who can speak to this more precisely. What we did was we went through and looked at the display of the data in Medicare Compare and made some kind of nominal suggestions about being more clear about what premium you would pay, including both the premium for the plan and the base premium.

And then we also had an exchange in that conversation -- I think you'll remember this, and if you want to take it over, you can, but this notion of it's a little bit more valuable to a plan -- could be viewed as more valuable to a plan to hand out a benefit where they get

a load on top of it than to give them a cash rebate where the load doesn't come to the plan. And then I think the Chairman said something like I wonder if we should look at that.

MR. HACKBARTH: I think I did say that.

[Laughter.]

DR. MILLER: Right. And so I'll get with the Executive Director and sort of figure out what happened to that thought.

DR. REDBERG: So if I understood the examples correctly, I thought -- I could follow what you were saying just to a point, because I thought beneficiaries would make a choice of the more efficient plan if they got the 101 base premium, but the difference in Miami, for example, was $500, or whatever it was, more that they would have to pay for fee-for-service choice in Miami reflective of the higher cost there than they would in a lower-cost area. And I think that would definitely make a difference to beneficiaries.

DR. BAICKER: Slide 13 [off microphone].

DR. REDBERG: Pardon?

DR. BAICKER: I thought Slide 13 [off microphone].

DR. REDBERG: I'm looking at Table 5, but I think it's very similar.

DR. BAICKER: Yeah. So my point was just that the dollar amount difference between MA and fee-for-service is the same in each case. So the dollar amount I think will drive choices. But if you look in Portland, it's, you know, $77 different in each case. It's just -- oh, no, it's not -- yes, it is. Don't make me subtract in public.

[Laughter.]

DR. BAICKER: And so you can see the delta between the two is the same in each bucket. It's just slid up or down off a different base.

DR. LEE: So the delta -- the difference between fee-for-service and MA that's across three examples, that number is the same. It's who's paying for that difference. That varies. But one clarifying question -- I mean answer, why the delta stays the same, it's because we have not modeled how the plans are going to bid differently, and these examples are very different rules. So presumably in the real world, that delta is going to vary because the plans are going to bid differently in response to different rules of --

MR. HACKBARTH: The plans might bid differently because they believe that beneficiaries would behave differently --

DR. LEE: Exactly.

MR. HACKBARTH: -- under the different scenarios.

DR. MILLER: But can we just hit -- because I thought -- everything everybody said was true. But I thought what Rita was driving at was how strong the incentive is for a beneficiary to move with her statement. And I think the thing I might tease out, if I understand your question -- and, again, everything everybody said was true. In the first example, Medicare is still paying at $100, in round numbers. The beneficiary can purchase fee-for-service in Miami even though fee-for-service is, you know, in round numbers 1,200 bucks. In that instance, the beneficiary could -- if we chose to give them all of the premium difference, could benefit to the tune of, you know, several hundred dollars in premium rebate in this illustrative example if they chose the managed care plan. And then there was this whole exchange of, like, what kinds of signals, what do people move, and the baseline they're moving from all depends on, you know, a lot of -- you know,

economics and psychology.

In the second instance, if the beneficiary stays with fee-for-service, they have to pay to stay, and then, I think, whatever the arguments are about the psychology and the economics of the first case, the signal there I believe would be stronger. You know, now I have to pay $400 to stay in fee-for-service versus would I get a $300 rebate if I moved to MA?

DR. BAICKER: But in either case, if you're -- in Miami, if you're in fee-for-service, you have $408 more in your pocket than if you had chosen MA -- less. Less, less, less. I said that backwards. In either case, you have $408 less in your pocket if you stayed in fee-for-service than if you picked MA. It's just how much money you have in your pocket varies, but in every case the delta is the 408. So then it comes -- so the economics in some sense are the same. It comes down to the psychology. Do I feel differently about, you know, starting in the middle and gaining 200 versus losing 200, or starting at the top and losing 400 versus neither? People may react differently. They may send a different cognitive signal. But the financial incentive seems fixed in all of these different --

it's $408.

DR. MILLER: [Off microphone.] I agree with that, and I think maybe it's more of a feeling than an economic point. Are people going to -- if you have to write a $400 check versus receive a $400 check in the mail, is that a difference, and I might be inferring what Rita was driving at. I suspect what she was driving at is if that person has to write a $400 check, it's going to be a bigger deal than if they receive a $400 check.

DR. REDBERG: That's correct. that is what I was driving at. And, I think that is what Kate was saying, too, but --

DR. MILLER: [Off microphone.] -- and it's just the psychology --

DR. REDBERG: Absolutely.

DR. MILLER: -- of getting a check versus writing one, and --

DR. REDBERG: But, I think that's a very important distinction, and especially because the difference -- the fee-for-service difference, I think, is really provider-driven in those areas. It's not patient-driven. So, it's not like they moved to Miami because they want to have more

services, you know, there are a lot more doctors per capita or a lot more services per capita, but not a clear quality difference there, and so it certainly makes sense to me to have that reflected in premiums.

MR. HACKBARTH: Would it make a difference -- might it also make a difference whether it's a question of receiving a $400 check in Miami or receiving the equivalent amount of money in terms of gym memberships and added benefits? There might be a different behavioral response between getting a check in the mail -- Bill Gradison has made this point on several occasions -- as opposed to benefits that they may or may not value highly, or they may or may not use. That's also a potential area for different response.

DR. REDBERG: We all agree that if you had to pay more for the more expensive plan, that would make a difference in people's choices.

MR. HACKBARTH: I think there's some --

DR. REDBERG: I'm pretty certain on that.

MR. HACKBARTH: -- foundation for that in the behavioral economics literature, but I'm not an expert on that.

DR. HOADLEY: So, yeah. I mean, I think, to your -- I was going to make something similar to your last point, that the -- I mean, right now, it is not a $408 cash difference. It's a $408 alleged value or actuarial value or something, that when you sort of look at the plans, it's actually sometimes hard to see the additional value that shows up there.

But, I think the other thing that it's sort of pointing out, that constant $408 difference, is that both the second and third example are mostly about -- and the third one does it even more than the second one -- about asking people to pay the geographic variation difference. I think that's where I start to stumble, because several people have started to make the point that it's not like the beneficiary can really make that change. I mean, it seemed like the first behavioral response I get is figure out how to change our zip codes. So, if I live in Miami and I've got a kid in Portland, I'll just switch my address to Portland and I just saved $400, $500, and you could have some interesting stuff going on like that.

But, beneath that --

[Laughter.]

DR. HOADLEY: Because there are -- I mean, I don't know. There's a lot of people whose addresses aren't actually where they live because mail is going to children's houses and stuff. So, there's a practical issue there that's ultimately in the margins of this.

I mean, I do think we have to think, also, about if you start to go down these routes, I mean, it's really sort of embedded in Julie's caveat about quality. I mean, we are right now just sort of assuming MA is MA is MA and we know that there's a lot of variation. So, if, in fact, in one area the MA plans are not very integrated, just doing the minimum they need to do to meet the requirements, we shouldn't necessarily be considering those the same way as in an area where we're really talking about integrated plans that are doing the kinds of things we'd like to see.

The other thing it seems like is there's obviously a low-income issue here that we're going to have to tackle if we're going to go anywhere down this, and right now, because it's the states who are the ones picking up the Medicare premiums, if suddenly States are either going to be in the position of saying, well, everybody in Florida has to now switch to fee-for-service if you're going to stay in the

Medicare savings programs, or the Medicare savings programs' costs are going to go way up for the State of Florida -- and, of course, part of that's Federal cost -- I mean, you might -- if we're ever going to go down this route, and I have some real qualms about it, we might want to think that's a good opportunity to think about federalizing Medicare savings and at least saying, okay, this is all a Federal problem now and not sharing it with the States.

But, I just think there is -- I mean, I think this is a terrific analysis because it really does lay out what's going on, I think, in an extremely clear way, and I really liked it for that. But, as a policy response to it, it lays out what to me are a lot of really serious problems with following the kind of inclination of saying suddenly to somebody in Florida that we just increased your costs by $400, or you have to join whatever passes for Medicare Advantage in Florida, a lot of which isn't very good.

MR. HACKBARTH: Of course, some people would say a lot of what passes for fee-for-service in Florida is not very good, either.

[Laughter.]

DR. HOADLEY: For any one beneficiary, they're not

necessarily getting -- I mean, a given beneficiary picking their providers carefully may not be part of what's going on with --

MR. HACKBARTH: Well --

DR. HOADLEY: I mean, I agree, that's a --

MR. HACKBARTH: I just want to underline this point that both Jack and Kate have made, how they characterize the difference between the second and third option. Kate used the expression, you know, who bears the risk of geographic variation, and we believe that beneficiaries can really, if we give them strong enough incentives, can they change that. That was an interesting way of putting that point and, I think, a provocative one.

Of course, the other way that some people would look at that, and they'd say, well, it's really not about expecting beneficiaries to change geographic variation. This is more an equity issue across regions and taxpayers. If you have two taxpayers in Portland and Miami who pay the same Medicare taxes and have the same income all their life and one is getting out twice as much money every month from Medicare, is that an equitable system? But, I think as a matter of efficiency, it probably isn't going to drive

consumer behavior to eliminate geographic variation, but it might be justified on equity grounds, or some might try to justify it.

DR. BAICKER: That's an important issue to think through. The flip side of framing that equity would be to say, you have two beneficiaries in Portland and Miami and they've been paying in the same amount and they want the basic, the cheapest Medicare package available to them. Why should the one in Miami have to pay more in premium?

DR. MILLER: [Off microphone.] If I followed your point, it's because it's more expensive in Miami.

DR. BAICKER: Right, but I'm just saying, if you're going to make an equity -- I understand --

DR. MILLER: [Off microphone.]

[Laughter.]

DR. BAICKER: That's right, or hides because it's near the water.

[Laughter.]

DR. BAICKER: No, no. But, the equity point is, why would -- just because the health care system in Miami is more expensive, you could make the equity argument, they both paid in. They're both entitled to Medicare. Why are

you charging the poor person in Miami more?

DR. MILLER: [Off microphone.] For the behavior of the provider --

DR. BAICKER: For the behavior of things beyond their control. Right. So, I think you could make the equity frame go either way.

MR. HACKBARTH: Let's continue here. Cori, and then we'll go over to this side.

MS. UCCELLO: I really like the way that this has been framed so far, and it put much more eloquently what I was struggling with in my head. But, as we're thinking about this now, we're assuming now that, well, in the fee-for-service world, beneficiaries pay the same out-of-pocket regardless of where they live, and I don't think that's true. So, how -- what is that geographic distribution in out-of-pocket costs now versus what it would be under these different options? That might be helpful for us to be either more or less comfortable with some of these more geographic differences.

MR. HACKBARTH: Yeah. So, now you're talking about not just the premium, but the out-of-pocket --

MS. UCCELLO: Right.

MR. HACKBARTH: -- cost sharing at the point of service.

MS. UCCELLO: Right.

MR. HACKBARTH: Bill Hall, and then Kathy.

DR. HALL: Julie, I think you put this together as a feasibility model of how we might make these comparisons between MA and fee-for-service, and understandably, you picked what might be argued as extremes. I mean, certainly, Florida is an extreme, and I don't know Portland that well, but I have a feeling that it's an extreme in the other direction. And, it seems to show some interesting differences.

But, how difficult would it be to now start to expand this model and maybe get areas of the Midwest involved and other parts of the country and see whether the extremes that you see here are reflected throughout the rest of the nation?

DR. LEE: We can --

DR. HALL: I know you can do it, but --

DR. LEE: No, it's the -- all the data for the analysis that's all there. So, we can actually look at examples that are more in the middle of the distribution.

We picked Portland and Miami to highlight the differences, but, yes, they are kind of outliers in the two extremes.

MS. BUTO: Picking up on the geographic difference point, I think it would be helpful to maybe have a better sense of the pros and cons of using sort of a nationally set base premium versus a locally set base premium. I understand the points that Kate was making about why should Miami pay more. In some sense, they're not responsible for some of that variation. But, I'd like to understand better what might drive -- or what we think might actually make a difference in paying more accurately for the services provided, and I have a feeling that something that has more local influence would give us more -- in some sense, more accurate payment for the services that we're paying for in Medicare between fee-for-service and MA.

But, I'd be interested to know, maybe in the next round, what you think the pros and cons are of moving away from a nationally-based payment -- which I know we've always had, but we've also had the AAPCC. So, there are a number of things that have a very local flavor to them, and the question is, in my mind, which would get us closer to what we would consider an appropriate payment in an area.

DR. MILLER: So, one thing we could do in trying to write this up -- and Jim, if I remember correctly, this is kind of part of the larger synchronization chapter or discussion -- maybe what we'll do is we'll try and put a box around this and say in these two options you have local and national. We're going to try and summarize some of this exchange and pick up other ideas that occur to us.

I'm very interested and willing to do this. The thing I'm just a little bit -- if you could just say a few more words -- when you said, which is more accurate, you know, you caught this exchange here about how you could frame equity one way or another way. When you say "accurate," do you have a thing in your -- because I would still -- I'm going to stop.

MS. BUTO: Well, the problem I'm having is using a national base premium can be very -- it may feel equitable, but is it really the appropriate contribution Medicare should be making by area, given the options that are available? In other words, we tend to go to these national rates and national premiums, but I do wonder whether -- what the balance is between equity and, in some sense, appropriate payment.

DR. MILLER: [Off microphone.] I think this could be an interesting essay to see if it gets to what you're going after.

MR. ARMSTRONG: Building on some of these same comments, first, I just want to say that the analysis and the way those slides were built was really fantastic. I mean, this has been kind of a structural issue that we've raised off and on, whether it's in MedPAC or elsewhere around the Medicare program, for a long time, and I've never seen four or five slides that kind of put it together and help us really zone in on, okay, well, so what are the questions and the implications in different choices, so I really want to applaud that.

Kate, I thought you did a great job of kind of helping us understand one versus two, and in particular two versus three and what that really means, and I look forward to kind of figuring out, well, now that we've understood the issue, what are the policy solutions to that. I'm not quite sure what they are.

But, I would just say, what struck me more than anything through this is that what we're trying to do is we're trying to synchronize payments between Medicare

Advantage enrolled programs and the fee-for-service program, and I think that's an important goal and we should really be pushing that. But, frankly, I'm beginning to wonder if there isn't, like, a different and perhaps bigger question, and that is how do we synchronize Medicare program costs from one market to another around our country. Inevitably, you have to sort of deal with some of that when you're dealing with our real agenda, the synchronization between MA and fee-for-service.

But, boy, Glenn, to your point early on, $626 versus $1,151 fee-for-service average cost, it is, like, how can you not ask what really is driving that? What explains that? And, how enormous, it seems to me, the opportunity for rationalizing the Medicare program spend would be if you could just sort of squeeze that gap by 50 percent. I know that's a totally different question, but, boy, it's hard for me not to leave this conversation and imagine work in front of us in the next year or so without saying, well, where do we spend time on questions like that.

MR. HACKBARTH: Let me pick up with Scott's point there. So, would you put up that Slide 7 again, Julie. So, we have the fee-for-service difference of $626 versus the

$1,151, and then the median MA plan difference of $703 versus $743.

Kate, let me go back to you, be devil's advocate here. So, you said, well, beneficiaries maybe shouldn't be held responsible for reducing variation, but this suggests that if we gave people really strong incentives to move into MA plans, in fact, that would do a lot to address geographic variation.

DR. BAICKER: And I think I wouldn't argue at all against having beneficiaries feel that full delta, so that the incentive part is the difference in fee-for-service versus MA in Miami is enormous, and it's much smaller and the other way in Portland. So, in Miami, there will be a big incentive to pick the lower-cost plans if beneficiaries face the full delta, and I wouldn't argue for dulling that incentive. The question is, should they also be paying more for the cheapest plan available to them than people in Portland are paying for the cheapest plan available to them. We still want the incentive to pick the cheapest plan available, but the difference between the geographic base versus the non-geographic base is even if you pick the cheapest plan, if it's based on the local cost, the person

in Miami is going to be paying more than --

DR. NERENZ: [Off microphone.] -- it's not much different, though.

MR. HACKBARTH: But, doesn't the MA plan suggest that the gap would get dramatically smaller?

DR. BAICKER: Yes, yes, yes. In this example, yes, and that seems -- if everybody switched to the cheapest plan available. The argument for not having beneficiaries bear any of the base -- the cost of the baseline geographic variation is if everybody picked the cheapest plan available to him or her, then would you want them to be paying the same thing, or would you want, if everybody picked the cheapest plan, do you want the people in Miami to still be paying more? Now, how much more they're paying is going to get smaller, but we're talking about the principle -- yes, and that's good, and we're all hoping that we move towards more efficient delivery in this way.

But, the question in principle is by not allowing a geographically varying base, you are saying, even if you pick the very cheapest plan, we're still making you pay more, and that -- you framed the equity as why should the taxpayer have to pay more, and the flip side is why should

the beneficiary have to pay more, which, of course, raises the question, why is anybody having to pay for this, and so how you're dividing that pie.

MR. HACKBARTH: [Off microphone.] I think I saw Jay's hand go up --

DR. CROSSON: I was just going to make the same point, which is that, I mean, what we're really about here, it seems to me, is to try to introduce cost conscious choice at the time of -- I can't use the word "enrollment," but the time of enrollment or non-enrollment, at the time of choice. And, if in so doing in those, you know, Miami-Dade-like markets it drives a lot of people to Medicare Advantage, then it creates a new dynamic, which, presumably, if you're in fee-for-service -- if you're a provider and you're in fee-for-service practice and you don't want to be part of an MA plan, all of a sudden, you've got to think pretty hard about your responsibility or your collective peers' responsibility for driving those costs and may, in fact, change the fee-for-service costs over time.

DR. HALL: This is looking to your next round, when you're bringing it again. Others have thought this through, and I have no idea what they've come up with. And,

in particular, there have been people supporting the concept of premium support. I'm not here to advocate. I just would be interested to know how they dealt with this issue in trying to think through how the funds would be broken down between high-cost and low-cost areas in some of the premium support plans that have been put forward in public discussion. Thank you.

DR. LEE: So, most premium support proposals, actually, they stick with the national premium. So, in determining Federal contribution for the Medicare coverage, I think all of them, it was nationally set.

DR. HALL: Thank you.

DR. NERENZ: I was just going to emphasize a point that we had a couple minutes ago. I thought there were all sorts of really interesting, fascinating elements to this analysis, but one of them was the extent to which the so-called lowest-priced plan really did not vary that much between Portland and Miami. That was very surprising. And, then, I think a number of these other things follow, that you want to reduce this regional variation. Pushing people into MA plans in high-cost areas like Miami would certainly seem to be a way to do that. It seems to be happening.

DR. HOADLEY: I mean, on this immediate point, we should be careful, though. Here, we are just using an N of two, and the distribution of MA is not as wide as fee-for-service, but it's still wider than this example would do. And, it's actually interesting to note that the penetration rate is almost identical in these two markets, despite the dollar difference. So, that sort of goes either to the inefficiency of adding benefits as opposed to cash or people's stickiness or whatever.

MR. HACKBARTH: That is striking, the penetration rates, and I suspect that in Portland, part of the issue there is that at least before the Affordable Care Act, Medicare was paying like 139 percent of fee-for-service cost to MA plans in Portland, and so they were able to offer really attractive benefits relative to fee-for-service to the point that in some parts of Oregon, basically providers said, "We won't take you as fee-for-service. We want you to enroll in this MA plan," primary care physicians, for example. It was so rich.

Now, the Affordable Care Act, obviously, is reducing those added payments in places like Portland, but they're still going to keep a significant piece of that.

They don't go all the way back to equivalents, the MA payments relative to fee-for-service. So, in a place like Portland, it is a 15 percent difference in perpetuity, and so that is one of the reasons why even with costs low, MA penetration is high in Portland. And I suspect the same thing is true in Minneapolis, to some degree, and some of the other low-cost markets.

DR. HOADLEY: And to the extent that bids aren't really, in a sense, maybe true bids because of the whole benchmark system, I mean, that also affects how we look at those two $700 figures.

But I actually wanted to make a different point, which is I think it may be we probably need to be careful about thinking about the difference between talking about these beneficiary incentive kinds of issues and the geographic variation obviously get intertwined, but they're also separable issues.

In the Part D world, it's actually instructive. There, you don't have a fee-for-service alternative, so all the benchmarking is around bids, and you actually get 2:1 ratios of geographic variation from some states to other states for a product that should by theory be a lot more

constant geographically. The distribution system for drugs, there is not the same kind of issues that you have for doctors doing different kinds of procedures.

Now, you could have doctors prescribing more drugs in one area versus another, so that probably is part of it. But it's striking that you get that 2:1 ratio without these complicating factors and raises some of the same equity or the inability to sort of make those differences go away, and whether risk adjustment kinds of factors are another potential complication in how we think about these geographic differences across areas.

MR. HACKBARTH: Another notion that I had as to why the MA bids are so much -- the difference is so much smaller between Miami and Portland is that we know from other research that a big part of the geographic variation is not in physician and hospital kind of services. It's in home health and DMS, and I suspect -- I don't know this, but the MA plans in Miami, one of the first things you probably do is get a grip on home health and really manage those things very tightly, and there's a lot of quick savings there, relatively easy savings, without having to intrude much in medical practice. That would be my hypothesis at

least.

Other thoughts on this?

MR. ARMSTRONG: Just to your last point, let's also recognize, though, that hospital utilization rates are three- and four-fold, depending on which markets that you are looking at, and you can't explain that through the demographics.

DR. CHRISTIANSON: And we have been talking about behavioral responses on the part of consumers to this, but I would expect there were behavioral responses on the part of providers. If I was a fee-for-service provider in Miami, the first behavioral response would be to merge. Merge. To take that to the extreme, if there is one health care system in Miami, I don't think the MA rates would be what they are now, right? I mean, they'd be much higher.

We are assuming that somehow everything is going to drop to the MA rate now, but I think a longer-term behavioral response couldn't actually mitigate that to some degree. I mean, we've certainly seen providers respond to changing financial incentives by merging in other markets, and the extreme markets would sit here.

DR. MILLER: If I could say one thing, if you

could give me just one of the brackets, everybody immediately -- and given the way we set this up, it is not surprising -- gravitated to what does the beneficiary pay for fee-for-service in Miami and the implications and the geographic variation inequity and all of that. I just don't want people to forget the reverse is try in other markets, and I think sometimes in this debate, people forget that. They focus in on the fee-for-service, and given the way we set up the example, the first example, the premium purchases, fee-for-service, it encourages everybody to think that way.

But the other thing that happens across the country is some markets, you're paying to stay in MA, and it also goes to some of Jon's last point and something that Bill Gradison said earlier. Depending on how much movement you get out of fee-for-service, that reference point, which is MA is used as a leverage and its negotiations becomes a question, and how you keep kind of fee-for-service in that reference point in this system, I think, is something we have to keep an eye on as well, because if they consolidate and drive, as Jon said, the private-sector prices into that bid, then it is not 740 bucks anymore.

MR. HACKBARTH: Do we know anything about what rates MA plans pay in a market like Miami? You might think that because there are a lot of providers that they might have leverage to get rates even below Medicare rates by providers one off against the other. We don't know anything about that?

DR. MILLER: So, Carlos or Jeff, when you did that analysis where you were looking at that at the aggregate level, did we look at all inside the markets? Do we have the capability?

Here is a mic next to Jim.

DR. STENSLAND: So hospitals is the same as fee-for-service pretty much across all the country, whether you're in Miami or Portland.

For physicians, what we hear anecdotally is that in some markets, they pay maybe a little bit more than fee-for-service, and in some markets, they might pay a little bit less than fee-for-service. And Miami could be one of those markets where they actually pay maybe a little less than fee-for-service because of all the competition amongst the individual physicians and maybe something with their practice style. Maybe these visits are eight-minute turn

visits more often down there.

MR. HACKBARTH: Okay. Any other concluding comments on this?

[No response.]

MR. HACKBARTH: Okay. Well done, Julie. Lots of interesting questions raised.

So now we will have our public comment period.

MS. McILRATH: Sharon McIlrath, AMA.

I just wanted to say one thing about the Part B drugs. I think you might want to look at some other government policies, specifically -- I don't know all the details of it, but with the Avastin and the Lucentis, I know that part of the issue for the ophthalmologist has been the lower-cost drug was never approved for FDA for use in the eye, and they have actually tried to get that changed, unsuccessfully.

And then the compounding rules sort of added into the problem. They also tried to go and get a national coverage decision regarding whether or not the use of the Avastin was approved for the eye. They have had to go separately to each of the contractors to get that.

I don't know how often that that is playing out in

any other drug, but I know it is an issue with that drug.

MR. HACKBARTH: Okay. We are adjourned until 9 a.m., 9 a.m. tomorrow.

Have fun in the snow, everybody.

DR. MATHEWS: The public website says 8:30 tomorrow. The website was changed after I circulated this.

MR. HACKBARTH: So 8:30 is the real time?

DR. MATHEWS: 8:30 is what was on the public --

MR. HACKBARTH: Okay. 8:30 a.m. tomorrow.

[Whereupon, at 3:39 p.m., the meeting was adjourned, to reconvene at 8:30 a.m. on Friday, March 6, 2015.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, March 6, 2015
8:30 a.m.

COMMISSIONERS PRESENT:
GLENN M. HACKBARTH, JD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
SCOTT ARMSTRONG, MBA, FACHE
KATHERINE BAICKER, PhD
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
CORI UCCELLO, FSA, MAAA, MPP

AGENDA PAGE

P R O C E E D I N G S [8:30 a.m.]

MR. HACKBARTH: Okay. Good morning. We have two Part D-related sessions this morning, the first on generic prices and the role of nonpreferred generic tiers, and then one on risk sharing in Part D.

So, Anna, are you ready to go?

MS. HARTY: Good morning. Jon and Glenn, you have asked about the market factors leading to recent concern about drug price increases. In this presentation, Shinobu and I will discuss the possible factors associated with shortages and large price increases in some generic drugs, as well as the potential relationship between price increases and generic tiers in Part D.

Over the past few years, two related trends in the generic drug market have sparked concern: drug shortages in hospitals and large price increases of certain generic drugs. Shortages mainly affect cardiovascular, anti-infective, and central nervous system drugs. Because generics accounts for over 80 percent of the prescriptions dispensed in the United States, over time shortages and price increases may create cost and access problems for patients.

A number of factors have been raised as being responsible for shortages. The cause of drug shortages most frequently cited is a delay in the manufacturing of a drug due to quality concerns. Between 2011 and 2013, GAO found that 40 percent of shortages were caused by these types of issues.

Sterile injectables are the most common type of drugs affected by shortages. Their market is concentrated. Often less than three manufacturers produce each drug, and each manufacturer has limited production capacity. When one manufacturer experiences a delay, the limited production capacity of the remaining manufacturers hinders their ability to meet market demand.

GAO also identified possible causes of shortages that were less frequently cited in the literature, including shortages of raw materials. The drug industry frequently attributes shortages to low reimbursement rates from payers such as Medicare. However, we do not consider low reimbursement to be a likely cause of drug shortages.

The usual complaint is that the ASP plus 6 system shifts demand to higher-cost drugs. However, even if this is true, it doesn't mean that there's a shortage of the

drug, just a shift from one drug to another. Furthermore, the types of drugs most heavily affected by shortages are not reimbursed under the ASP plus 6 system.

Drug shortages can lead to increases in prices of generic drugs. A number of other factors also contribute to price increases. Most involve a lack of competition in the market for generic drugs; that is, there may be too few manufacturers producing each individual drug.

Market concentration may be due to the existence of barriers to entry, such as high cost of inputs, of complying with regulation, and of production. Other factors that may contribute to price increases are anticompetitive behavior such as mergers and acquisitions that create monopolies and market exit by manufacturers.

When producing a drug becomes less profitable, some manufacturers will exit the market, leaving it vulnerable to monopolies with few limitations on their ability to raise prices.

A number of possible solutions exist to combat shortages and price increases. First, Aaron Kesselheim of Harvard Medical School proposed that the FDA could waive the generic drug user fees for low-profit drugs facing

shortages. Generic drug user fees were introduced to expedite the process of reviewing generic drug applications. Waiving them for drugs facing shortages could reduce barriers to market entry.

Second, increasing price transparency has been suggested as a way to reduce or prevent price increases that are not justified by market or other factors.

Third, recent legislation requires drug manufacturers to notify FDA six months prior to a potential shortage of any life-sustaining drug. The goal of early notification is to give FDA time to develop solutions or approve alternative manufacturers.

Fourth, Kesselheim also proposed that the FTC should increase oversight to make sure generic manufacturers are not engaging in anticompetitive behavior, citing an example of a manufacturer that strategically acquire its competitors, creating a monopoly and drastically increasing its prices.

A final suggestion is that FDA could expedite the approval process of manufacturers that plan to produce a drug that is facing a shortage or a large price increase.

We presented this information mainly to answer

your questions about recent trends in the generic drug market. As you can see, most of the policy actions listed here are up to FDA and FTC and outside the purview of Medicare.

Now Shinobu will discuss the potential relationship between price increases and generic tiers in Part D.

MS. SUZUKI: Because the rise in the use of nonpreferred generic tiers by Part D plans has coincided with the increased attention paid to large increases in prices of some generics, some have speculated that plans may be using the nonpreferred tiers to limit access to generic drugs with large price growth. Use of tiered cost sharing has been a common feature in many plans that are offered under Part D. This is because plans have to balance a need to provide enrollees with access with the need to control growth in drug spending.

Plans use tiered cost sharing to encourage their enrollees to use lower-cost drugs. Generics are on a lower tier with cost sharing that are lower than brand-name drugs, and brand-name drugs that are on a preferred tier have lower cost sharing compared to those on nonpreferred brand tier.

Having preferred and nonpreferred brand tiers helps plans negotiate rebates with brand manufacturers, particularly for those that face competition from other brands or generics in the same therapeutic class.

This is usually not the case for generic drugs. Over time plans have moved towards more tiers. Most plans now use a five-tier formulary, including preferred and nonpreferred generic tiers, preferred and nonpreferred brand tiers, and a specialty tier with higher cost sharing applied in that order.

So what may be driving this trend towards using nonpreferred generic, or NPG, tier? Unlike brand-name drugs, plan sponsors do not negotiate rebates with manufacturers of generic drugs based on their tier placement, but sponsors may still find value in using an NPG tier.

For example, large increases in prices may mean that, in order to remain competitive, they need to encourage the use of lower-priced generics or share more of the costs of higher-priced generics with their enrollees through higher cost sharing applied to drugs on NPG tiers.

Plan sponsors may decide to apply the lowest cost

sharing to certain therapies. For example, they may want to use a zero dollar co-pay or very low co-pays for therapies that are recommended based on evidence-based guidelines and are available in generic forms. So NPG tier may be used to distinguish other drugs from those that are evidence-based.

Another possible reason may be to ensure that their benefits are actuarially equivalent to the Part D's defined standard benefit. With more prescriptions accounted for by generic drugs, a higher cost sharing on generics may be needed to ensure that benefit offerings continue to meet the actuarial equivalence test, or there may be other reasons.

The use of an NPG tier has the potential to lower the overall program costs if it encourages enrollees to use lower-priced products. But if generic drugs that are used by low-income-subsidy enrollees are on higher tiers, it can increase Medicare's payments for the low-income cost-sharing subsidy.

In 2015, most PDPs and MA-PDs are using two generic tiers, preferred and nonpreferred. About 90 percent of plans use an NPG tier, with over 80 percent of enrollment in those plans. If one of the goals for using an NPG tier

is to encourage the use of lower-priced generics, that may work for non-LIS enrollees, but is not likely to work for LIS enrollees because they would pay the same statutorily set amount for both preferred and nonpreferred generics. Medicare's low-income cost-sharing subsidy would pick up the amount above those set in law.

Thus, if shifting some of the cost to enrollees is one of the goals, that is more likely to succeed with LIS enrollees. But when we compared the tier structure among PDPs that qualify as LIS benchmark plans to non-benchmark plans, we found that benchmark plans are less likely than non-benchmark plans to have an NPG tier. That is, it appears that the goal may not necessarily be to shift costs to the low-income subsidy.

We also found that the difference in co-pays for drugs on NPG tiers compared to preferred generic, or PG, tiers are generally modest, typical difference of between $3 and $7. Co-pays on PG tiers for the largest PDPs are often very low or zero dollars.

We also examined how the formularies of the largest PDPs treated some of the generic drugs that experienced large price increases and found that those were

not always placed on NPG tier, and the placement varied across plans. These findings suggest that factors other than cost may be motivating plans to use the NPG tier.

So we looked to see if there were certain classes that were more likely to be placed on PG or NPG tier. What we found is that NPG tier is the most common placement for generic drugs covered by plans, with only a small share of generic drugs placed on a PG tier, typically less than 15 percent of all covered generics; while over 40 percent were placed on NPG tier.

We also found that some generics were placed on brand tiers. The tier placements did vary across drug classes. For example, cardiovascular agents were more likely to be placed on PG tier than other classes. Typically very few antineoplastics and central nervous system agents were placed on PG tier.

When we examined some of the guideline-recommended therapies, they were mostly placed on an NPG tier or higher tier, a pattern similar to the overall distribution of generics across tiers.

Cost-sharing implications of generic drugs placed on an NPG tier rather than on the preferred generic tier

tend not to be large, typically a difference of $3 among PDPs and $7 among MA-PDs. However, effects of cost-sharing difference and, therefore, potential effects on low-income cost-sharing subsidy could be much larger when generic drugs are placed on brand tiers. A typical co-pay difference between the preferred generic tier and brand tiers can range from $40 if placed on the preferred tier to $90 if placed on a nonpreferred tier. That is, if an enrollee filling a generic drug placed on a brand tier could face -- an enrollee filling a generic drug placed on a brand tier could face a co-pay that's equal to the full price of the drug up to $90, whichever is lower. The co-pay difference could be even larger if an enrollee were to fill his or her prescription at a pharmacy that does not offer preferred cost sharing; that is, at a pharmacy that's not one of the pharmacies that offer lower cost sharing.

Based on our examinations of some of the potential reasons for using an NPG tier, we find that the use of an NPG tier does not appear to be related to higher prices or clinical criteria. Although there are some variations across drug classes, NPG tier appears to be the primary generic tier for plans that use two generic tier structures

for the following reasons:

First, we found that NPG tier is the most common placement for generic drugs for plans using two generic tiers across all classes. Overall, over 40 percent of generics are placed on NPG tiers, a much higher share than the share of generics that are placed on PG tiers.

Second, the increase in co-pays for drugs placed on the NPG tiers compared to PG tiers are generally modest, averaging about $3 among PDPs and $7 among MA-PDs.

Finally, given that co-pays on PG tiers are typically very low, and in some cases zero dollars, the co-pays for NPG tiers may be comparable to what these plans would have charged if they had one generic tier.

As a comparison, in 2007, when most plans had a formulary structure with just one generic tier, a typical co-pay was about $5. While typical co-pays for NPG tier does not raise immediate access concerns, it could raise concerns for access and for the low-income cost-sharing subsidy if NPG tiers are increased substantially or more generics are placed on brand and specialty tiers.

MR. HACKBARTH: Okay. Thank you.

DR. MILLER: Glenn and I were just setting some

context up here.

So the first half of this is to directly respond to questions, and I suspect it crosses other Commissioners' minds, why you're reading about shortages and price increases on the generic front and whether there's a connection to the policy that goes on in Medicare. Most of this was -- all of it was secondary research, and we tried to lay out for you what other people are saying, and so we can have a conversation of how much of that overlaps with Medicare or not, if you want to talk about that. A lot of the outsiders who are talking about this talk about FDA and FTC types of solutions, if there are solutions.

And then the second half on generic tiers, we're starting to see this phenomenon where there's two tiers showing up, a higher- and lower-priced generic. We're trying to figure out why that's going on, and most recent -- and so in some ways I think this is -- we're going to keep our eye on this and sort of see what's happening here.

And also something that we need to sort through is in the recent call letter or rate announcement, there was a change to that tier. And I know for myself, I haven't unpacked exactly the implications of all of that, but that's

also something. So CMS is kind of aware of this and looking at it, and that might be another point of either conversation or future conversation here.

MS. SUZUKI: So the change that CMS was proposing is mainly related to labeling of the tiers. By calling the second generic tier nonpreferred generic tier, there may be a perception that it's difficult to access or it's not recommended. And so rather than calling preferred and nonpreferred generic tiers, they're proposing to call the nonpreferred generic tier just a generic tier because it is acting like the primary generic tier. And for plans that have the preferred tier that are cheaper than the main generic tier, they could continue to call it a preferred generic tier.

MR. HACKBARTH: Okay. Clarifying questions?

MS. BUTO: Thank you for the presentation. I guess I'm not aware -- can you give us a better sense of how many generic drugs are on the brand tiers? And how would you characterize them? Are they certain classes of generics? Are they certain high-cost generics? Can you give us an example of how common this is?

MS. SUZUKI: So roughly 30 percent are on brand or

specialty tier. Sometimes it's based on the formulation of the drug. Most of the other formulations are on a generic tier, but maybe one formulation that -- or dosage is on a different tier, a brand tier. That may be one of the examples.

There may be some classes that are more likely to be on brand tiers, and I could get back to you on the exact classes where they're more likely to be on brand tiers, but antineoplastics and CNS agents that we mentioned in one of the examples are classes where a lot of it are on NPG or brand tiers.

DR. MILLER: And, Shinobu -- and I'm sorry to interrupt here. So, you know, I brief CMS on everything that we're doing, and so this was late on Wednesday, and you and I haven't caught up since then. There was a comment in the briefing where somebody said that this issue of what can be put for generics to be -- what can be put on the name brand versus the generic tier was also implicated in their call letter, and that was the thing that I hadn't really caught up to.

MS. SUZUKI: Right. So my recollection --

DR. MILLER: I hate to put you on the spot. We

can come back to this [off microphone].

MS. SUZUKI: So my recollection is that one of the guidance that CMS is giving plans is that the labeling of the tier has to be representative of the majority of the drug that's on that tier. So if you're calling it a generic tier, it has to be mostly generic. And, similarly, if it's a brand tier, it has to be mostly preferred or nonpreferred brand. It doesn't preclude having some small share of drugs that are not exactly matching the labeling.

DR. MILLER: That's what they were saying to me [off microphone].

MS. BUTO: I'm still mystified, and maybe we could get more information on this. Would they be generics that are just so expensive that the plan wants to charge a large co-pay to discourage use and there are plenty of alternatives in the generic tier? Or are they generics -- what I wonder about is are they generics where there are very few choices and so the plan feels it can charge the beneficiary more to use that particular drug.

So, anyway, we can get back to that later, but I'm just curious.

MR. KUHN: I'm just trying to get a better sense

of the order of the magnitude of the shortages issues out there and just thinking both pre and post ASP plus 6 or Part D. And is this something -- have shortages always been with us, or have they become more prevalent since the payment systems have changed in the last decade? I'm just trying to get a sense of -- and if they have changed, you know, is it -- you know, kind of just a sense of the order of magnitude of the shortages changes that we're seeing.

MS. SUZUKI: So the data we've seen starts around 2007, and it has grown since 2007. We haven't really seen data prior to 2007, so it's hard to say whether, you know, that timing matches what you -- the ASP implementation.

The things that we found is that there are a lot of factors that seem to be related to shortages. One of the interesting things that we discovered in reading about this is that generic manufacturers are having quality issues, may have to change the line or, you know, put in some capital to improve their facilities, and that's when they may be deciding to switch to a different line. And the increase in shortages are coincided with the patent expirations of a lot of brand blockbuster drugs.

DR. MILLER: And that was the point that I was

hoping would come out in this exchange. That's the other thing that's been happening in the last few years, is all this is coming -- all the people are coming off patent. You're getting much more competition that's driving the price down, and that's kind of what everybody wants to happen. But then there may be a cut point that you kind of run into.

MR. KUHN: Thank you.

MR. HACKBARTH: Okay. Clarifying questions? Jay?

DR. CROSSON: Mark addressed it.

MR. HACKBARTH: Okay. Mary and then Scott.

DR. NAYLOR: So I don't know if this is when guideline recommended medications, and I am wondering how much. I mean, you talked about in solutions, the critical role of evidence, but how much do clinical guidelines influence where the placement of drugs on tiers?

MS. SUZUKI: So this was a selected set of guideline-recommended therapy, not an exhaustive study, but when we looked at a couple of them, we found that they were all over the place. Mostly, they were on non-preferred tier as with all the other generic drugs.

In some cases, some of them might be on preferred

tier. Sometimes they're on brand tiers as well.

DR. NAYLOR: [Speaking off microphone.]

MS. SUZUKI: We didn't --

DR. NAYLOR: Thank you.

MR. HACKBARTH: Scott.

MR. ARMSTRONG: Mark, I think this is a question for you, coming back to the comments you were making in trying to set this up. I have to say I'm still kind of confused about what is the problem that we are trying to solve, really from a Medicare program point of view. Is the problem that there are shortages of certain drugs that Medicare beneficiaries are not getting access to that they should? Is the problem that the prices for drugs are going up, and therefore, we're concerned about the financial burden on the Medicare program? Is the problem that the way in which these tiers are being built is misleading to our beneficiaries and we want to -- I mean, I think they are really interesting, and frankly, I don't know that much about how this part of the program works.

But I just have to say I'm not sure how I am supposed to look at this from a Commissioner's point of view.

DR. MILLER: That's fair. I'd like to kick this to Anna, so --

[Laughter.]

DR. MILLER: Actually, she probably would do a better job with it.

I think you can look at this a couple of different ways, and I'll try and reverse-engineer into an answer.

For Shinobu's piece and the expansion of the -- or the change in the tiers, I mean, that is something in Part D. We have been watching, will be watching, and it raises all the questions that, in a sense, started happening with Kathy and ended with you, which is what do we think is going on here. Is this therapy driven? Is this price driven? It could be good in the sense of it's managing the cost of the program and the beneficiaries getting a good signal or something else, and we don't know.

At this point, I think we are starting to unpack and not willing to say this looks like a good development, a bad development.

One thing Shinobu said -- and I am not sure how much people tracked on it -- is it might be helping the plans hit their actuarial equivalency by taking some set of

drugs and moving them off to a higher cost tier. Is that a bad or a good thing? It could be relatively simple what the plans are up to.

So that is what I would say about Shinobu's piece, that, indeed, it is very much in our turf. It looks like some things are happening inside the benefit, and we should, as always, keep an eye on it. Much like the risk conversation that we are going to have next, is this sort of indicating something going on in the underlying benefit?

Anna's piece, the problem, the main problem is you guys keep asking questions. Let's be really clear about where that came from. We wanted to make sure that we came back to you and at least put something in front of you.

I don't know whether that is a Medicare issue, per se. I mean, it could be pipelines are ending -- or, I mean the patents are ending. Just like everybody expects, generics enter, prices get driven down, and now we're at this point where manufacturers are asking whether they want to continue to pursue a drug.

Just for other reasons that people have been asking about, we are looking at ASP-plus 6, anyway, as a percentage versus a flat add-on because of some other

questions people asked. If you do think there is a link there, in a way, you are already up to looking at it, but I don't know how hard the connection is between that phenomenon and a specific Medicare phenomenon, rather than just a price-being-driven-down phenomenon.

Does that get you anywhere closer to your -- because Anna could take this.

MR. ARMSTRONG: Part of what I heard is that there could be a long list of possible issues we will want to explore. In a way, we are trying to learn more about those issues before we really narrow the scope.

DR. MILLER: That's a much more succinct way to say what I just said.

[Laughter.]

MR. HACKBARTH: On the specific issues of shortages, we're the Medicare Payment Advisory Commission. Some people have alleged that Medicare payment policies are a contributing factor. It seems to me sort of a basic responsibility of ours to take a look at that and evaluate it and see whether we think there's any truth to it, and it is really akin to what we do to updates, where we consider whether Medicare payment rates assure adequate access to

quality care. It's just sort of the same enterprise.

No conclusion is driving it or no particular fear. It is just a basic monitoring responsibility that I think we've got.

Clarifying questions? Jon.

DR. CHRISTIANSON: Just a couple of questions in terms of whether you have looked at some things or not that didn't appear here on the slide.

Back to Mary's point, the discussion of copays and structured copays relative to encouraging or discouraging adherence to treatment guidelines, did you look at that question in the context of MA plans versus Part D? Because you would think the MA plans would be sensitive to that because they may be able to capture some of the cost savings from, for instance, treating chronic illnesses, that adhering to treatment guidelines might result in fewer medical care costs, so they would maybe have stronger incentives to think about structuring the tiers in that way.

MS. SUZUKI: So we didn't look at the MA-PD plans specifically for the guideline-recommended therapies, but overall, the average copays for MA-PDs are a little bit higher. The $7 difference between preferred generic and

non-preferred for MA-PDs is higher than the $3 on average for PDPs, so they have a stronger incentive built in there.

And I believe the cost-sharing amounts on preferred generic tiers on MA-PDs are also higher than PDPs on average.

DR. CHRISTIANSON: So that wouldn't necessarily support the idea. Okay.

So the second question I had was we're going to hear, I think, in the next presentation some arguments that beneficiaries tend to look at premiums when choosing a Part D plan and are less able to digest all the information or the cost implications of different copay schedules and co-insurance schedules.

So do you see the tiering structure being different in more competitive markets for Part D plans than less competitive markets? And my thinking on this is that in more competitive markets, there may be more pressure to keep premiums low, and that is counter-balanced by higher copays and so forth. Is that anything that you have taken a look at?

MS. SUZUKI: We have not looked at copay variations by market forces.

DR. CHRISTIANSON: Okay.

DR. MILLER: Well, the only thing I was going to say is we'd have to probably first figure out how we classify competitiveness --

DR. CHRISTIANSON: Sure.

DR. MILLER: -- in a market, which is not to say no, but we haven't done that. And so I'm thinking her answer to your question is not yet.

DR. CHRISTIANSON: I think it actually relates more to the second session this morning, maybe, in some ways than this session, anyway.

DR. MILLER: And maybe we should -- we will have to huddle after all this, anyway, but whether we could think about how to classify markets is kind of an interesting question.

MR. HACKBARTH: So we will continue down on this row.

DR. HOADLEY: It's on this point. I mean, since most of the -- especially in the PDP side, most of the plan -- and really even on the MA side, an awful lot of the plans are national in scope and have pretty much the same benefit design nationally. That makes it harder to -- you really

have to be looking at the small subset of either local PDPs, which are very few, or a slightly larger subset of local MAs. So I think that's unlikely to be much of a factor.

MR. HACKBARTH: Alice.

DR. COOMBS: So in the reading material at page 10, the selected generic drugs with the largest increase in price, there is a real wide variation. You have digoxin, which has been with us since countless ages of time. You have very old medications here.

My question is -- and you have fluoxetine as well -- are there any models out there that actually can predict what's happening in terms of what happens to the long-term generic drugs and the influence of other things, such as a competing drug company or some other extenuating factor that influences how a good old-fashioned time drug has been with us forever and it suddenly increases by 17,000 percent? I am just thinking about what other factors are there, and if there are factors in some kind of discovered process, then is it possible that we can predict the longtime drugs like Colchicine and things like that going forward? And that is of interest to me.

MS. SUZUKI: So I don't think we have thought

about predicting the trends, but I think it depends on the reason for the price growth. For example, if it is the shortages that are causing the prices to increase temporarily, it may resolve after the shortages are resolved as well. If it is the market structure, it may be a different issue. If there is only one or two manufacturers who can charge whatever price, that could be a different length of time to resolve.

DR. MILLER: Well, I really do think it is back to Scott's point of trying to unpack all of this. You can see the price falling. You end up -- let's just say in this example, a shortage, the manufacturer can raise their price. That may bring people back in, and in a sense, you have this phenomenon. My guess would be we're going to see more of this to the extent that if competition drives these prices down and manufacturers get out, we are going to see more of this bounce where a generic price could turn around and go in the other direction.

But again, if it attracts manufacturers back in because of that, then it starts to mitigate that again. It is just a question of how much intervention there should be in order to assure that a drug gets to a patient. I think

that is the real hard question, whether it's access or propping up a market.

DR. NERENZ: My question is quite a bit like Scott's. I think in reading the materials, I was trying to think through how much of the phenomena that we see here are driven directly by CMS rules and requirements over which we presumably have some oversight, and how much is within decisions made within an individual plan.

So the question is related to Slide 6. It is actually in the notes, not in the slide itself.

You talk about how CMS requires that when developing their formulary structure, plan sponsors must use standard industry practices. Now, I'm not close enough to know. You go on and then illustrate a couple of examples. My question is, are those two additional things sort of the essence in all of the standard industry practices, or is there a whole other domain and these are just two examples?

What I am trying to sort out is how much is this driven by things that CMS defines and constrains and requires in the formulary structure, and how much leeway do the plans have?

MS. SUZUKI: Are you asking about whether plans

need to have two tiers?

DR. NERENZ: That might be an example. There is this phrase, "standard industry practices." It is not familiar to me. I'm just curious. How should we understand that?

MS. SUZUKI: My interpretation of that phrase is when you are calling a tier a "generic tier," it should mostly have generic drugs.

DR. NERENZ: But beyond that, are there a whole other set of standard industry practices that are relevant to this?

MS. SUZUKI: I don't --

MR. HACKBARTH: A more generic way to ask the question, what we see in Part D plans, is it materially different from what's happening in employer-sponsored plans, which might be an indicator that there is at least some regulatory effect here?

MS. SUZUKI: So the structure of D plans are very similar to commercial plans that are available out there. Is that sort of what you are getting at?

DR. NERENZ: I guess. I keep coming back to this phrase because what that suggests to me is that -- let's say

we observe a certain phenomenon that there is something going on in a particular tier and we around this table say, "Well, that is strange. Something ought to be done about it." Well, the question is, what exactly would we say to change it? If that is, indeed, a standard industry practice, should that phrase go away?

I'm sorry I can't articulate better.

MR. HACKBARTH: Yeah.

DR. NERENZ: But it does get to this question of what's just purely within the business decision authority of plans and what's required by CMS.

MR. HACKBARTH: Well, I'm not sure this will help, but sort of a premise of the Part D program was that we were going to use a consumer choice model, give private organizations substantial latitude to define the product -- in this case, drug plans -- and depend on competition among those plans to produce lower cost and quality services for the beneficiaries. That's sort of the basic philosophical underpinning of the Part D program.

Without having any specific knowledge, I would assume that so CMS is saying, "If that's the goal, when we look at establishing regulations on Part D plans, one of our

reference points is standard industry practice," which may be what's happening in the private sector outside of the Medicare program. And so if they see all these different tiers being used among private plans and multiple generic tiers, that may be an indicator that this is a standard industry practice driven by competition and market, and they may not want to interfere with it.

Does that make sense, Shinobu?

And so they are just using industry practice as a reference point for regulation, which I think would be a sensible thing to do.

DR. MILLER: And completely consistent with that -- and Jack and Shinobu, I'm sure are deeper than me on this -- there is a process within CMS, whatever the larger regulatory framework is, of looking at bids and trying to make sure that bids don't have very anomalous structures to them that might indicate somebody trying to select or do something odd, and I think some of that is referring to that, where there is some oversight of the bids and whether they look like they're structured in an odd way.

MS. UCCELLO: So I'm really intrigued by how different drugs get placed into the different tiers, and I

am discouraged by the indications that prices and clinical criteria don't seem to be playing necessarily a huge role.

But prices here were measured based on price increases, and I'm wondering if we looked at prices, whether that would be better correlated or whether price increases were correlated with a change -- or price decreases with a change in the tier, so looking at -- if you're looking at price changes, looking at whether the tiers changed, but using prices themselves rather than increases to look at the static tier.

DR. REDBERG: Thanks. I thought it was a great presentation and very interesting chapter, which I am glad we're covering.

I'm just curious because I couldn't find any. Do any plans put any definitions of what criteria there are for non-preferred? Because all I see is lists. These are preferred generics. These are non-preferred. They don't list any criteria anywhere.

MS. SUZUKI: Not that I'm aware of, and it seems like non-preferred is the primary tier. In some plans, it is usually less than 15 percent of their generics are showing up on the preferred tier.

DR. REDBERG: Comment. It is definitely something that has happened in the last year because I just noticed when I am refilling prescriptions for patients, it's become very confusing because now the dropdown menu in the electronic record has like eight different tiers, and they don't know and I don't know what makes them go into different tiers. It is the same as they have been on for a long time, and of course, they don't list what the copays and the prices are. It just lists a lot of different preferred class -- well, in preferred class 2. And it's very overwhelming, and it's just happened. And I'm getting more and more requests from pharmacies for clarification. So it's clearly something that is affecting all of our beneficiaries.

DR. HOADLEY: I can comment on a couple of these things that came up, but I can wait until the next round to do that.

My clarifying question was kind of trying to quantify a little bit on the drug shortages and the drug price increases. I don't know if you found anything that sort of gave you a sense of how many drugs, whether it is by volume of use or just by counter drugs, have been affected

by shortages as well as by the price increases.

MS. HARTY: So FDA and the American Association of Health System Pharmacists, or whatever it is, they have slightly different -- they both have lists, and they have slightly different numbers, but the health system pharmacists, one is usually a little bit higher, but it's usually -- between 2011 and 2013, it usually ranged somewhere between 200 and 300 drugs on each list, I think.

DR. HOADLEY: This is for shortages or for price--

MS. HARTY: For shortages. I think that the average was 224 in 2013.

DR. HOADLEY: So a fairly substantial number. And for price increases, do you have any sense?

MS. SUZUKI: So we looked at CMS' NADAC average survey prices, and there we found about 50 percent experiencing price increases between November 2013 and November 2014 and the other half experiencing decreases.

The one thing I would note is that we don't have data prior to this period, so it's hard to say whether that's, you know, more drugs experiencing price increases in this period compared to earlier prices or not.

DR. HOADLEY: I mean, my anecdotal sense on the

increases is that the ones that have the really big sort of -- I mean, a 10 percent increase on a $2 drug is not a big deal, even though 10 percent could sound big. But the ones that are these 1,000 percent are still pretty isolated cases. But I'm not sure of that. But it does sound like the shortages is not just a handful, but it's a fair number.

And I also seem to recall there was some change in FDA rules at some point about how shortages had to be reported. Do you know anything about that?

MS. HARTY: I'm not sure what year it was -- It was definitely within the last three -- that they passed a law that says that manufacturers have to report a drug that has a potential shortage at least six months prior to that potential shortage.

DR. HOADLEY: And as I recall, that was partly to allow them to have a better chance to address it in terms of, you know, dealing with encouraging another manufacturer to get in -- but also, you know, from a reporting point of view, we may know more about shortages, so thinking about trends over time could be affected by changes in reporting rules.

MR. HACKBARTH: Other clarifying questions, Bill?

DR. HALL: No.

MR. HACKBARTH: Anybody else?

[No response.]

MR. HACKBARTH: Okay. Round 2. Could I kick off Round 2? I just want to sort of go through this in my plodding way.

Medicare pays for drugs, either directly or indirectly, through various payment systems, Part D being one, Part B being another, but there are also inpatient drugs that some of them are in short supply, and outpatient departments, and I just want to sort of go through the different Medicare payment mechanisms and see if we can identify where there might be potential issues that Medicare is contributing to the shortages.

So let's start with Part D. So Medicare's involvement in Part D is not direct in setting prices. The prices, for better or worse, are set by the private market, and so at best, any Medicare Part D effect on drug shortages would be very, very indirect.

In Part B, Medicare is directly paying for the drugs -- well, paying for the providers who supply the drugs, but the mechanism that's used is based on average

sales price, which presumably is a market mechanism. Medicare isn't artificially pushing down that average sales price, and so presumably Medicare's effect is not to create the shortage. And feel free, anybody, to jump in and say no, you got this wrong.

DR. MILLER: I believe that's true, and there's always the lag in the data.

MR. HACKBARTH: Yeah. And then, you know, if we go to inpatient hospital, there Medicare is paying a bundled rate. The actual purchase of the drugs is done by hospitals, often through group purchasing organizations and the like, but Medicare's role in setting the price for those drugs is, again, very indirect at best.

Under the outpatient payment system -- actually, you're going to have to sort of remind me, Mark.

DR. MILLER: You got it. It's either ASP plus 6 or it's package --

MR. HACKBARTH: On a bundled basis. So, again, it's either a private average sales price mechanism or it's through a bundled payment where the hospital is buying the drug, and that's a private mechanism.

I don't see first-order effects at least where

Medicare is creating a potential shortage through its pricing mechanisms. It's not -- Kathy?

MS. BUTO: ESRD and DME are two other --

MR. HACKBARTH: Yeah.

MS. BUTO: Because in DME, I think it's drugs provided through DME or covered by Medicare, and it's like albuterol sulfate and things like that.

MR. HACKBARTH: Yeah.

MS. BUTO: And then, of course, ESRD, there are some drugs specific to the ESRD population. So it would be easy enough to figure out whether the drugs predominantly provided through those mechanisms are in any way shortage drugs. I don't believe they are.

DR. MILLER: I don't either, and remember, ESRD moved to a bundled payment, which the drugs are now part of the bundle. I don't hear the shortage issues there, but I could be uninformed. And, similarly, DME has moved to a competitive structure, but I don't know whether the drugs are yet underneath it. I'd have to double check that. That's a detail I don't have.

If I were -- I agree with everything that you said. If I were trying to still, you know, make the

argument, I think some of the people who have tried to make this argument say, yeah, I know ASP is a market price, but you have this percentage add-on, and that drives people to, you know, the higher-priced drug, which you're already talking about, so you're well aware of that for other reasons. And, you know, again, does that just mean we're sorting people to a higher-cost drug, but they might come back and say but it makes the generic less profitable and, therefore, people less willing to manufacture it. But, again, it's a market-based price, and whether you buy the 6 percent is exaggerating that or not exaggerating that phenomenon is...

MR. KUHN: And, Glenn, I think at least when it comes to the ASP plus 6, when Medicare went from the old AWP, the average wholesale price, to ASP plus 6, during that two-year conversion time I think there were some market interruptions at the time as people made that adjustment. But I think it was just during that transition period. I think the one that a lot of people cite is IVIG, was a -- you know, had some disruptions in the market at that time. But I think once they go through that transition, it seems to have been pretty stable since.

DR. CHRISTIANSON: So we seem to be focusing on things that Medicare policy might or might not influence, with almost the implication that if Medicare policy doesn't influence them, then it's not in our purview. But I would make the sort of parallel here to what we do when we think about physicians. We have a chapter on physicians, and we say it's important to track access, but we don't think Medicare policy has a big effect on physician supply in and of itself. It has an indirect effect. But we care about beneficiary access to physician services.

And I think a similar argument can be made here. I think we should care about beneficiary access to different kinds of drugs. Well, what does access mean in this context? One way to think about it might be over time can we track what beneficiaries have to pay for certain types of drugs, and is that changing over time? And is it changing in a way that is really potentially having an impact on beneficiaries being able to get the care that they can afford?

So maybe we should be thinking about what are some high-volume, high-use drugs for beneficiaries or drug classes for beneficiaries. And do we want to know what

beneficiaries are paying over time to access those drugs financially? And just as a way of tracking what's happening to beneficiaries in the Medicare program. It's not -- so that's where I'm kind of interested in understanding some of these more fundamental market things that are going on and trying to play out in the long term what impact might they have on beneficiaries.

MR. HACKBARTH: And I absolutely agree with that, Jon. So I think it is important for us to monitor and understand, and I think that was one of the points that Mark was making. That's why we're doing this, is to try to understand these phenomena that are very important, including to Medicare beneficiaries.

Then there's a separate question. If we see a problem, what is Medicare's role in trying to do something about it? And those are each important activities, and I didn't mean to suggest that we shouldn't be monitoring.

DR. CHRISTIANSON: No, but I'm wondering whether we are monitoring in a systematic way beneficiaries -- the impact on beneficiaries of changing, whether we should think about something parallel to what we do when we say, well, what's access to hospital care? Are hospitals closing? Are

they not closing? What's happening to physicians, participating physicians, not participating physicians? It would require a whole new way of thinking about how we'd want to do that with drugs, but maybe we should be thinking about it given the sort of what seems to me is really interesting changes, and what Rita said really struck home to me, too, in terms of these are things that are important to beneficiaries; they aren't just sort of interesting design issues and a co-pay structure.

MR. HACKBARTH: So let's get other people back into this.

DR. CROSSON: So assuming that we're going to continue over time this discussion, I'd like to understand a little bit more about the dynamic, Shinobu, that you referred to, the potential for tier creep, if we want to call it tier creep, as a consequence of needing to meet the actuarial equivalence test. So I think I understand that, you know, the benefits need to be equivalent, that there is a defined standard benefit, that someone looks at the plan or the bid to make sure that it fits with that.

But I'm having trouble understanding whether or not in order for that to happen, it forces plans to put

drugs in higher tiers with higher co-payments that they wouldn't otherwise necessarily need to do, and as a consequence then drives the LIS subsidy. I mean, is that actually the mechanism or am I missing something?

MS. SUZUKI: So the first question on actuarial equivalence, we don't know for sure that's the primary reason plans are placing different drugs on different tiers. But we have heard that because CMS sets a maximum on -- maximum co-payment amounts for each tier, that sometimes if you're capped on the brand side, you may have to charge higher co-pays for generic drugs to make sure that your benefit is equivalent to the standard benefit.

DR. CROSSON: So then the corollary is you couldn't offer -- in other words, it has to be exactly actuarially equivalent? You can't offer a better value? And one consequence of that is then, as I said, it drives Medicare costs up because it drives a higher LIS subsidy?

MS. SUZUKI: If you were to provide a more generous benefit, then that portion would be an enhancement to your benefit. So you're no longer a basic standard. So it depends on what kind of plan you're bidding for. If you're an enhanced plan, you can certainly have a more

generous coverage than the standard. But for the basic plan, by law you have to be equivalent to the standard benefit.

And what we were concerned about is whether -- if LIS enrollees did not respond to those financial incentives the way non-LIS enrollees do, by placing some of the generics on higher tiers, it could potentially increase the subsidy costs.

DR. MILLER: But we weren't seeing a pattern that strongly suggested that. So for the moment, in trying to parse through this -- and, again, we're trying to parse through it at the same time, so you may not end up with a completely satisfactory answer here. So just holding the LIS portion of your question aside, I don't know that it's about increasing the cost of the program. A plan may have decided to enter the market at a certain price, and in evaluating what the basic premium pays for, they have to offer something that is actuarially equivalent. And so within that, they're trying to move things around on co-payment tiers to hit that. And I'm watching Shinobu as I'm saying this, and you need to nod and shake your head at appropriate points to make sure that I'm not taking these

guys way off track.

You know, in this isolated example, I don't think we're talking about -- again, holding LIS to the side -- that that increases or decreases cost. The plan has decided to enter the market at the price and then is trying to structure within that benefit the actuarial equivalence and saying the basic subsidy covers this. And then if they enhance or don't enhance, then that's a separate decision.

Then we ask the question, I wonder if moving to these tiers kind of drives a bit of LIS action into this, and at least so far, Shinobu, we're saying we don't see a strong pattern there. But this would be the kind of thing that we would keep looking at, because there on the second half of your question, then it could be driving a program cost. Any help or just --

DR. CROSSON: That's helpful. Thanks [off microphone].

DR. MILLER: All right.

MR. HACKBARTH: Anybody want to follow up on Jay's question or issues raised there?

MS. UCCELLO: Jay raised the question I was going to raise. I just want to clarify here that plans, when

they're offering -- insurers offering multiple plans, they're keeping where they put the drugs on the same tiers between the plans. They're only changing the cost sharing of those different tiers. Is that right? So the formularies and where they put the drugs, where they sort the drugs into the different tiers, if they have a regular plan and an enhanced plan, that sorting is the same? So something in the standard plan isn't preferred generic and then it goes to nonpreferred generic with another plan. Is that correct?

MS. SUZUKI: I think typically a plan sponsor does use the same formulary for all the plans, although I don't know that it's always the case, but they may -- like you said, they may change the cost-sharing amounts on those tiers.

MR. HACKBARTH: So they're not required by regulation to use the same structure.

MS. SUZUKI: The cost-sharing amounts --

MR. HACKBARTH: No, in terms of where to locate a drug.

MS. SUZUKI: Oh, they're not required -- right.

MR. HACKBARTH: They are not required to do --

MS. SUZUKI: Right. They could have a separate formulary if they --

MR. HACKBARTH: Yeah, okay.

MS. UCCELLO: So the levers that they have in order to reach this actuarial equivalence is actually both where they place the drugs as well as the cost sharing.

MS. BUTO: I just wanted to get back to Jay's example of -- because I'm trying to understand it. If the plan reduces cost sharing, in other words, doesn't move to the nonpreferred tier, wants to be more generous, does that plan premium end up being more or less? Are there selection issues? Because maybe that drives a certain kind of patient away or -- I'm just curious what that impact would be and why you couldn't somehow figure out how to make that actuarially equivalent, a plan that's much more generous on the generic side than -- you know, than putting things in the nonpreferred tier.

MS. SUZUKI: So I don't know if this will address your question, but the way the test works is that the plan has to use its own claims to meet the actual test. So the utilization of that plan members determines how much -- what the new benefit parameters, whether you meet the actual

equivalence test.

MS. BUTO: It is just an aggregate of the plan members experience that drives the test. Okay.

MR. HACKBARTH: Okay. Continuing Round 2, Bill Gradison.

MR. GRADISON: Briefly picking up on Jon's excellent point, it would seem to me that this discussion might lead to adding some questions in that annual survey of beneficiaries that we do on this subject. I don't recall that we have had any in the past that could be more specific about what we might ask, but it certainly, I would think, would want to include the experience of Medicare, particularly new Medicare beneficiaries to the experience they had just prior to coming onto the program, because we do have those two groups, cohorts or whatever, of people to example.

So I don't need to elaborate on it further except to suggest that we may already have a mechanism for pursuing Jon's point.

MR. HACKBARTH: Round 2. Jack.

DR. HOADLEY: So I want to try to pick up on a couple of different things that people have talked about.

My sense of the history of the two generic tiers in particular is that it came out of sort of two different instincts by different plans, and this is not sort of systematically something I have researched or that MedPAC has researched, but the sense was that some of the plans were sort of adding a cheaper tier to maybe have drugs that they particularly wanted to encourage or that were particularly inexpensive, and that's sort of the pattern that Shinobu described. So most drugs are on the non-preferred or what CMS now wants to call just the "generic tier," and then sort of there is the bonus tier up front that's cheaper, maybe zero, maybe a dollar or two for drugs you either especially want people to take, adhere to, or that are particularly cheaper.

But there were some other plans that sort of left the front tier, their regular tier, and added sort of a more expensive generic tier, and that seemed to be more out of a strategy -- and I say "seemed" because I haven't talked to plans about this -- to say, "We've got some expensive generic drugs. We want to be able to charge extra for them," maybe even doing a percentage coinsurance, which is another trend that is going on inside all the other things

that sort of complicates. That way, if they happen to have a $200 generic for some biological or something -- well, biologicals are probably not the place to go on this, but just an expensive drug, if you can, say, have a 15 percent non-preferred generic tier coinsurance, then you recoup a fair amount of money.

That was fairly rarely used for a number of years. Then in the last couple of years, we've seen a lot more of either type of these, though seemingly more of the former type.

I think one of the things that makes this a useful thing to think about is that, A, this is confusing, along the lines that Rita talked about and Shinobu talked about, even what are the labels, what does it mean when a generic drug is in a brand tier, and all these things are confusing, but also this point that there seems to be not enough relationship to clinical guidelines and clinical standards.

I mean, there is a general rule people are asking about, what are the rules that drive these things. There is supposed to be a P&T committee, a pharmacy and therapeutics committee, that is supposed to make a lot of these formulary decisions.

We don't have a good sense of how well that's monitored by CMS. They all have these P&T committees, but do the P&T committees mostly just address on- or off-formulary decisions? Do they really address this kind of micro decision about which tier placement and sort of how much? And I think that's maybe an area where some questions could be asked, either of CMS of what's the nature of that review or of the plans and what role sort of clinical criteria are playing.

You can make a case that if you're splitting drugs between two generic tiers that you want the ones that you really want adherence to that are important to take to be on that cheaper tier as incentives, but you can also understand the plan's incentive to say, "I want to be able to recoup more of the cost on expensive drugs." But when you get to the situation where all of the drugs of certain classes are on that second non-preferred or generic tier, then it kind of doesn't make sense from sort of a superficial point of view at least, and if it's going to make sense from a broad point of view, then I think that ought to be better understood. Some of these questions that CMS started to raise in the call letters seem to point to some interest in

doing that.

The actuarial equivalence stuff is where it gets really complicated, and just all this business of basic and enhanced plans, then this would be a different discussion. But one of the things I've been observing is that mostly when a sponsor offers two plans, while, yes, they generally do have the same tier structure, more and more there is a tendency to have different size formularies -- and Shinobu showed some data on this I think at the last meeting -- and have more drug on formulary, and that could mean also some resorting of drugs by tier, although I think that's less common than just the amounts.

But the odd thing is that most of the enhanced plans actually have higher cost-sharing levels than the basic plans, and that seems to be all tied in with what was being said about actuarial equivalence for the mix of members that are in that plan.

So because there is the selection that, Kathy, you were sort of alluding to, you have a different selection in your enhanced plans where the beneficiary is supposed to be paying all the enhanced value, not the program, but you end up with these sort of strange situations where it actually

looks like the enhanced plan is a lower -- is a higher cost-sharing plan, a lower -- I don't want to say "quality plan," but a lower value plan. And I think there is room to sort of look into seeing how is this all sorting out where are the selection factors playing in.

Then the ultimate review that CMS has that's statutory is to make sure that the tier structure is not done in a way that's discriminatory, and so you can raise questions when all of the drugs and certain classes are on one of these two tiers versus the other, is there a potential to discriminate and to encourage beneficiaries with certain health conditions to go in and to avoid a plan because of where the drugs are placed. And that's ultimately the strongest tool CMS has drawing from the statute in its arsenal to go about and review these formularies.

Again, it might be worth trying to understand better how that authority is being exercised and what's being done to make sure, because some of these things on the surface seems like they could be discriminatory in nature.

MR. HACKBARTH: I want to go back to the first part of what you were saying, Jack, and ask some stupid

questions.

So I'm focused on this notion of very expensive and sometimes rapid increases in prices for generic drugs. Generic means that there's not a patent involved, and so at least in theory, somebody can come in, another manufacturer can come in and make the same drug. That particular barrier to entry doesn't exist.

I assume that when we have very expensive generics, especially ones with rapid increases in prices, there are not multiple manufacturers in the market for that type of generic, that for whatever reason, we are talking about a limited number of manufacturers involved.

DR. HOADLEY: My sense is that is probably true most of the time, but there seemed to be example where that's not true, where there seemed to be -- I mean, one of the drugs that I think was high on the increases was some of the thorazine, and there are multiple manufacturers. That is a complicated drug for some other reasons, but it's not a sole-manufacturer kind of situation.

MR. HACKBARTH: So the price could be high, and there are multiple manufacturers because the ingredients are expensive. So it is a high price, but still the profit

margin isn't exorbitant.

But if it's a high price and big margin and a generic drug, all other things being equal, you would think that would cause new entry into the market.

Are there cases where we know of generic drugs that have high prices and high profits and there is an entry into the market? If we're trying to understand what the mechanism are that are causing high costs in generic drugs, it would seem that we would want to examine some of the underlying dynamics in these markets. There may be limited entry due to regulatory issues. I don't know. It just seems to me that that's an odd phenomenon, if it exists, high-price, high-profit generic drugs.

DR. BAICKER: And you would think that issues in terms of entry barriers and regulatory mechanics would be more serious for something like bio-similars than for generics and small molecules.

MR. HACKBARTH: Right. You would think.

DR. HOADLEY: There's been some industry -- I think we talked about this a little bit at the last meeting. There's been some industry shifts in the companies that make generics that some of them are being acquired by brand

companies. There's been some consolidation, and that probably has been a factor, at least anecdotally, in some individual cases, whether it's a brand company buying up and then kind of not wanting generics, say, in a class of drugs where they have a brand presence.

MR. HACKBARTH: Right.

DR. HOADLEY: Not the same product, but elsewhere in the class. I don't know if there's any specific examples like that, but certainly, as you have fewer companies in the business, there's fewer companies with the potential to sort of ramp up and enter on a particular product.

DR. MILLER: Just before you move to another person, I have one follow-up for Jack.

DR. BAICKER: My concern --

DR. MILLER: But if you're following up with Jack --

MR. HACKBARTH: I think Kate was following up.

DR. BAICKER: Just following up on that, one wonders whether the general regulatory environment makes existing as a generic manufacturer more costly over time, and then that would limit the number of players and the competitive pressures to keep prices down.

Is it that there are just fewer and fewer independent manufacturers overall? So even for something where the entry for a specific compound wouldn't be so onerous, there just aren't enough players, and so you're not in a competitive market place. It's oligopoly or whatever because the small number of players who can afford the fixed cost of operating in the market.

DR. HOADLEY: And, of course, getting even further out of MedPAC's jurisdiction, this is a global market, and a lot of companies are international companies, many not based in the U.S., and the ability for generics to compete in some of the overseas markets is not nearly as good. People talk about how other countries have a better handle on drugs than we do. We tend to have a better handle on encouraging generic competition than other countries, and so there's global factors going on that we probably won't address as a direct policy measure.

DR. MILLER: Well, implicating Scott's question early on, which is what is the problem we're trying to deal with here, the one thing I just wanted to -- you talked about CMS's oversight of the construction of the formulary and the tiers, and you made the point about discrimination

probably being the strongest tool, all of which I agree with and follow.

One of your other comments implied clinical decisions, and I just wonder there where that puts CMS in the decision process and whether that's something that they can handle. In a sense, we're sort of saying to the plans, "That's a decision you're making," and the attractiveness of the benefit to the beneficiary is in part driven by these decisions, where you tier things and where you pay.

I worry, if I understood your comment -- and that's what I'm driving at -- it could imply CMS making some decisions about what therapy is superior to another therapy, if you see what I'm --

DR. HOADLEY: I do.

DR. MILLER: And I may not have understood your point.

DR. HOADLEY: Well, the two places I could see CMS oversight -- and they may be doing -- one is enforcing the requirement that's in the statute that plans use P&T committees, and at the simple fact level, I don't doubt there's an issue, but the nature of which CMS has guidance, regulation that says what does that mean, what does that

translate into, and how independent do those P&T committees need to be. So that's one potential area of oversight.

The other is CMS -- and this is not one of the areas where they have been the most transparent -- in addition to their two drugs per class and protected class kind of things that we have talked about occasionally in terms of the formulary view, they have other drugs that are categories like drugs used in clinical protocols that they presumably require plans to include on formularies. So there's these other elements of what they expect and what they apply in their reviews of formularies that I have never found have been very transparent. It goes to such things as like in the hep C drugs, whether plans in the Medicare world would be free to pick and choose among the hepatitis C drugs or whether CMS will actually require them to include all of the competing products in that particular class of drugs, so some of that kind of oversight.

DR. REDBERG: To make this even more complicated, even for guideline-recommended therapies, you can't tell if they're being used for the on-guideline indication or off-guideline, and the same for label. As we know, there's a lot of drug reassessed off label, so it might look like it's

a guideline or a recommended, but it is really being used off label. And it's really a big issue and I think about to become a lot bigger issue because there are a lot more biologics on the market and specialty drugs that are incredibly expensive.

And also, something that we didn't to talk that much about yesterday when we were talking about Part D payment, but the orphan drugs that get approved -- and they are very expensive because they are supposed to be for rare diseases, but they are used off label for non-rare diseases, and they have that same price and protections. And that's something that is clearly affecting all of our beneficiaries. There are a few more very expensive drugs that the FDA is reviewing this summer for cholesterol lowing and for heart failure that have a lot of potential to really blow budgets as well as hep C. Already, the price of the hep C drugs is -- and I wonder how much that contributes to this actuarial equivalence if you have to have cost sharing of 25 percent and the overall expense has gotten much higher. Is that why copays are going up?

DR. HOADLEY: It's certainly a big reason why plans have moved to percentage coinsurance more often, and

the specialty -- any of the expensive drugs on a specialty tier are going to be handled by a percentage coinsurance. So, in a sense, that keeps it from going up nominally, but it allows it to go up in real dollars as the percentages go up -- I mean as the percentage of a higher number.

MR. HACKBARTH: Responding on this particular point, Bill? On this point, Kathy? If it's on this point, go ahead.

MS. BUTO: Yeah. It was really on the issue of evidence-driven or guideline-driven use.

I think this whole area is one that hasn't gotten very much attention. In other words, tiers are used to, I think, drive behavior based on cost and particularly as they go to percentage copays.

The guideline part is very unclear, whether it's off label, on label.

Use of tiers to drive appropriate utilization, if you will, or the right utilization for beneficiaries in a certain category of condition, that is a lot less clear.

So I think one thing this has sort of highlighted, particularly with the generics, is that the relationship between guidelines or the preferred medication for a given

condition isn't what is driving this, and if it needs to be more explicit, I think Jack is right that CMS's role would be to drive the P&T committees to a more active oversight of this particular part of the clinical practice.

MR. HACKBARTH: Okay. Continuing Round 2. Alice.

DR. COOMBS: So Jack said something that resonated with me, and the last piece about the international piece, I think is really important.

I am going to take it from the standpoint of inpatient shortages because I think it's really important. I work at multiple different hospitals, and about five or six years ago, there was a shortage in levophed, and levophed is a drug that is life-sustaining. We couldn't figure out why there was a shortage, and we were faced with a shortage in a very rapid fashion, such that we couldn't respond to it.

But I took the notion to call another hospital where I have privileges and said, "Do you have levophed?" They said, "We have levophed," and I said, "They told us at our hospital, it's a national-wide shortage." I think that some of the intricate details are such that the purchasing companies for various regional places where health delivery

system or hospitals may face a shortage based on whatever mechanisms that they go through.

There was a shortage on the diisopropylphenyl, which we -- it later to other countries came into the market and now produces -- purchasers will buy that drug from Rome. We get it from Sweden, and there is a place in Irvine. But the difference between the three drugs is amazing, and I think we assume that all of the drugs are the same, but there are some fine details in drugs in terms of the moieties in which they are sustained and especially for those drugs.

But we've been faced with shortages of drugs that are licensed to any like atropine. Atropine is on every single code card in the United States hospitals everywhere for resuscitative measures and in the ACLS guidelines. That one was hard one because it comes from a relative. Its cousin is the tomato. So it's something that is easily produced, and you just try to figure out, well, what is the overhead of producing atropine?

So for some of the issues, I think there are external issues that are just the cost of productivity, but the purchasing of the companies, what Jack said, I think is

really another factor that we didn't consider.

So if we were to take some of those rapidly increasing drugs that are on page 10, I think there might be details within some of the reasons why they are rapidly increasing.

Fluoxetine, there was a newspaper article about increasing suicide related to some of these, so I can understand some of the drugs going up and down based on prevailing side effects or things that people may be associated with it. So that is for inpatient.

For outpatient, gout, very common in our society. Colchicine. All of a sudden, Colchicine goes from a dime drug to three -- triple percentage increase, and there are details of why those drugs and why Colchicine would increase, and I'm wondering if there are external factors that we haven't considered, some of the things which Jack said, because access to Colchicine is really important for patients with gout. Although that may not be the scope of this Commission, but I think it's an important and direct relationship to the shortages that patients will face.

DR. REDBERG: Glenn?

Colchicine, in particular, it was generic and now

it's branded. You know, it's been around forever, but the FDA -- it was through some very quirky thing, the FDA allowed the company to assert a brand on it without the usual, and I think that's why it went up.

MR. HACKBARTH: So, I know Scott is in line here, and Bill Hall has been waiting patiently, and Bill Gradison, then we'll be about out of time. Scott.

MR. ARMSTRONG: Yeah, just briefly, I'm going to kind of go back. I thought Jon's comments a while ago were really excellent.

I would appreciate -- I think -- and maybe this is for the summer, at our retreat, but I feel like I'm still spinning my wheels a little around what's my role and my contribution as a Commissioner to this whole agenda. I feel like we're overseeing spending $600 billion worth of services per year, and I feel like I have a really good handle on the trend for spend on inpatient hospital costs and for outpatient services and home health, and I can kind of look at it all and we're making some judgments about how payment policy may influence whether we should be spending faster or slower and how it all kind of holds together as an overall portfolio.

And I haven't got a clue how much of that is being spent on drugs. I really appreciate the quick synopsis of this structure for payment around drugs and how kind of broken up it is, and that may be part of the reason why it feels like I understand it far less well than I do some of these other categories, but it just seems to me that -- I mean, I know my generic for Group Health, our generic costs have gone up more than 20 percent in the last year, and we're expecting drug pharmaceutical costs in future years to exceed the cost of inpatient hospital services.

Now, that may not be directly applicable to the Medicare program, but the next few years, we have to be paying attention to the investments that we'll be making in drugs more generally, and I think it just calls on us to have a better feel for how's that money going to be spent, and if there aren't many mechanisms for us to actually through these structures have influence, at least we ought to have a better understanding for what the impact on the future viability of the Medicare program will be.

MR. HACKBARTH: Bill Hall.

DR. HALL: First of all, I think you've taken a very arcane topic and made it at least semi-digestible, and

I appreciate that very much.

[Laughter.]

DR. HALL: I learned more from your paper than I probably knew for the last 20 years in this subject.

So, just to kind of recap -- and the idea here is what part of this is our business versus all the other regulatory agencies in the world -- first of all, I think Scott raised the important question, and thank you for it. What are we doing? What are we talking about here? Not on my watch, or whatever.

And, Jon answered that by saying, well, duh, we do this because it may affect the beneficiary in terms of costs and also efficacy, and I think we could all agree with that.

So, it seems to me there are two areas here, both of which have been mentioned, where we might want to really hone down on, and one is, and said by at least three or four people here, is there actually are data suggesting how drugs should be used in older people. We call them clinical guidelines and they've proliferated enormously. And, notoriously, they're not used very much in certain circumstances where things are not in the direct control of the caregivers doing the prescribing.

And, so, I think one of the benchmarks we could say is if there are irregularities and change in formulary, does this comport in any way conceivable to scientific guidelines that have been published and endorsed by a lot of agencies? I think we would make an enormous contribution if we took that.

And, the other is this business of shortages. I don't recall seeing a lot of shortages a decade ago, but now, in my institution, there's hardly a week goes by when something isn't suddenly in a crisis and a shortage. Now, sometimes it's understandable, an esoteric drug or something. But, more often, I think, as Alice has said, it's just that -- it's like a lot of shortages. It's not a shortage problem, it's a distribution problem. We see that with influenza vaccine in some years.

Incredibly, recently, we were out of certain statin drugs. You know, that may have been a good thing rather than a bad thing, but-

[Laughter.]

DR. HALL: As, I guess it was Osler [sic - quote by Holmes] who said, if all the drugs in the world were thrown into the sea, it would be to the benefit of people

and the detriment of the fish.

So, these things happen, but they often make no sense at all, and when shortages develop, I think one could reasonably say, is there some kind of market manipulation going on here, or what kind of poor planning or regulation is there?

So, two areas. Are we doing things -- are we comporting to our own guidelines? And, the other is, are shortages potentially manufactured, or is it just very sloppy thinking?

MR. HACKBARTH: Bill Gradison.

MR. GRADISON: I guess I'm picking up on the same point, so I'll try to be brief. I would caution about the use of the word "shortage." To me, a shortage means that the necessary medication is not available in a timely manner for the treatment of the patient. Now, what I observed during my Duke time and talking to a lot of hospital people is that it's very close to what Alice said. It increased the cost to the hospital because they'd have to add a person who's on the phone and on the Internet, right, checking around and finding where there is a supply, and then you get this informal network, and you may pay a higher price

because the seller wants a higher price. But, it doesn't mean -- it was in short supply, but it doesn't mean there was a shortage that impacted on the patient.

And, so, I just would enter, I think there's a tendency, maybe -- I'm not saying here, but there may be a tendency when the word "shortage" comes up to say that is almost always bad at the end for the patient in terms of appropriate treatment, and I'm not sure that that's necessarily the case.

MR. HACKBARTH: Okay. Just a couple observations, since this is one of my last opportunities. To me, there are only a few things that are clear here. One is how complicated all of this is, whether you're focusing on the issue of shortages or rapid price increases, and in part, that's because there are so many different players involved in this.

And, while I agree with Scott's point and the point made by many others that what's happening in drugs -- prices, shortages, development of new drugs, et cetera -- is very important to the Medicare program, very important to Medicare beneficiaries, both on cost and quality grounds, MedPAC only has so much time and so many resources.

And, so, it seems to me that the first responsibility of the Commission is to say, are Medicare payment policies -- we are the Medicare Payment Advisory Commission -- direct contributors to these problems, and that's sort of the most basic responsibility we've got. And, I'm not sure that the answer to that is no, but I think the answer may well be no.

Then, the next question is, well, to what extent do we want to spend our limited resources investigating all of these other very complicated phenomena that may be affecting the availability of drugs and the pricing of drugs that are not strictly Medicare policies, in particular, and I think they're all critical issues, but I think it could be an enormous amount of resources involved to really do it well with no direct output in terms of MedPAC recommendations to the Congress on how to improve the Medicare program.

It's going to be your call, not mine, on how you spend your time and resources, but as important as the issues are, if they're not Medicare-specific, then I think you've got to ask whether this is high productivity work. That's my two cents' worth.

Nice job, Anna. Thanks for that, and Shinobu, as always, good job.

Let's move on to our final session now, which is about Part D again and sharing risk.

[Pause.]

DR. SCHMIDT: Good morning. Shinobu and I are going to give you some information about sharing risk in Part D so that you can continue the discussion that you began last October. But, first, let me quickly answer a couple of questions that you had from the January meeting.

Kathy, you had asked about the total amount of Part D spending on biologics. In 2012, that amount was about $4 billion, or 4.5 percent of gross Part D spending. Of the $4 billion, about 90 percent was incurred by enrollees who reached the catastrophic threshold of the Part D benefit.

Jack, you had asked about the relationship between the increase in enrollment due to retirees joining Part D employer groups and the decline in the percent of enrollees with the low-income subsidy. We looked at that, and we think that about half of the decline in the percent with LIS is due to the influx of enrollees with employer groups. We

can go into this in more detail later if you like.

But now let's move on to the issue for today, which is sharing risk in Part D.

Here's what we'll discuss. First, we'll briefly recap some of the discussion from last time just to provide a framework. Then we'll walk through some of the patterns we've seen in Part D data from the reconciliation of prospective payments with actual benefits paid. We asked plan actuaries about the payment patterns we were seeing, and I'll describe what they told us. However, we also think that there may be a financial advantage to plan sponsors when they bid in certain ways, and we'll describe how that might work through a numeric example. We'll close by talking about next steps for this research.

To get us started, let's review a few things from last October's session. This slide describes some of the basic features about Part D. Medicare pays private plans to deliver outpatient drug benefits, and plans compete for enrollees mostly on the basis of their premiums. There are two types of Part D plans: drug-only plans that beneficiaries in fee-for-service Medicare can join, and Medicare Advantage plans that combine drug and medical

benefits.

Medicare pays for nearly 75 percent of covered basic Part D benefits through different types of subsidies, and the enrollee pays just over 25 percent through premiums. One piece of Medicare's subsidy is a capitated monthly payment that effectively lowers premiums for all Part D enrollees. However, specific plan premiums vary from one plan to another depending on whether the plan sponsor bids higher or lower than the national average. Medicare also has other pieces of its subsidy that offset some of the insurance risk that plans face, and we'll talk about those in a minute.

For about 30 percent of Part D enrollees with low incomes, Medicare also provides extra help with premiums and cost sharing, and this is called the low-income subsidy.

This slide lists 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 the enrollee premiums,

the plan has to cover the cost. Medicare risk-adjusts the direct subsidy to offset the incentives for plan sponsors to avoid higher-cost enrollees.

We've been spending most of our discussion talking about these last two risk-sharing mechanisms on the slide. 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. Risk corridors were initially designed to help get the market for stand-alone drug plans up and running, but that market is now well established. Another reason for them may be to provide a backstop to plan sponsors in the event that a large expense comes along unexpectedly, such as a new, high-priced miracle drug that lots of enrollees want to use.

This slide is a reminder of how individual reinsurance works.

Here we have the structure of Part D's standard benefit, and working from the bottom up, you can see there is a deductible; then the enrollee pays 25 percent, and the

plan pays 75 percent up to an initial coverage limit; then there's partial coverage in what has been called the coverage gap; and finally a catastrophic threshold. Notice at the top of the slide in white that 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. Medicare pays for 80 percent of covered benefits above that amount, so it's taking a lot of the risk for the highest spending enrollees.

You may remember from last time that about two million people hit the catastrophic threshold in 2012, and about 80 percent of those were enrollees with the low-income subsidy.

Here we're reminded about the current structure of Part D's risk corridors. After the end of the benefit year, CMS compares each plan's costs for actual benefits paid with what the plan sponsor bid. The sponsor has to pay for all benefit spending that is up to 5 percent higher than what they bid. They also get to keep any profits up to 5 percent lower than their bid. You can see that if actual costs are between 5 percent and 10 percent more or less than the bid,

the plan and Medicare split losses or profits 50/50. If actual costs are more than 10 percent different from bids, then Medicare pays for 80 percent for larger losses -- or gets 80 percent of the gains.

You may remember from our October discussion that in every year since Part D began, Medicare has, in the aggregate, collected risk corridor payments from plan sponsors. That tells us that prospective payments were higher than ultimately they needed to be, and plan sponsors got to keep profits over and above what was already in their bids.

Remember, the reason we're examining Part D's risk-sharing arrangements is because Medicare's payments for individual reinsurance -- shown here in red -- have been growing very quickly They're the fastest growing component of Part D program spending. You can see over on the right of this slide that reinsurance payments have grown by a cumulative 143 percent between 2007 and 2013. Meanwhile, program spending for the direct subsidy -- shown here in green -- has been pretty flat over time. Spending for Medicare's extra help with premiums and cost sharing to low-income enrollees -- in yellow -- is the single largest piece

of program spending.

Let me briefly tell you about the timing of Part D's bidding and reconciliation processes because they play important features in our risk discussion. Part D benefits for calendar year 2015 began on January 1st. But to get to that stage, plan sponsors had to submit their bids to CMS at the beginning of June 2014 -- seven months earlier. Those bids included the plan sponsors' estimates of average benefit spending, how much they expect to get in rebates from drug manufacturers, how much they expect to get from Medicare for individual reinsurance and low-income cost sharing, and so forth. CMS uses this information from bids to set the prospective payment amounts that Medicare pays to Part D plans each month. In July 2016 or so, CMS will begin its reconciliation process to compare Medicare's prospective payments for 2015 with the actual benefits that each plan paid. As the last step of reconciliation, CMS calculates whether Medicare owes the plan money under the risk corridors, or whether the plan was overpaid and owes Medicare money.

One piece of this reconciliation process looks at individual reinsurance. CMS compares Medicare's prospective

payments for reinsurance to the amount of catastrophic spending the plans' enrollees actually had. And remember that under our current risk-sharing provisions, Medicare is on the hook for paying 80 percent of catastrophic spending. When we look at the reconciliation data, it turns out that in recent years, for a growing majority of plan sponsors, Medicare ends up paying out more individual reinsurance money to the plans when they reconcile the payments. You can see this in the yellow bars. Positive amounts mean Medicare paid the plans. In other words, the plan sponsors have been underestimating how much of their covered benefits 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. You can see this in the green bars. Negative amounts mean the plans paid Medicare. This means that plan sponsors overestimated all the other covered benefits in their bids except for the catastrophic spending. So they got to keep at least 5 percent more than their bids in additional profits above and beyond margins already built into their bids, and many of the plan bids were in that outer region of

the risk corridors where benefit costs were 90 percent of bids or less. Plan sponsors have had to pay back Medicare with risk corridors because they were overpaid.

We conducted interviews with plan actuaries of large Part D plan sponsors as well as some consulting actuaries -- all of whom are very familiar with the process of preparing Part D bids. We asked them what might be behind the pattern of payments.

One idea that came out of these interviews is that some of the actuaries use smooth assumptions about trend to project what future benefit spending will be for their enrollees. In other words, some of them use the same assumptions about growth rates for spending across therapeutic classes of drugs or across the entire distribution of drug spending. However, those growth rates have differed a lot. Spending in most drug classes where there are generics available has grown more slowly than in classes where there are only brand-name drugs or specialty drugs. Using a smooth trend assumption has the effect of underestimating catastrophic spending and overestimating all other covered benefits.

The actuaries we interviewed also said that there

is a lot of uncertainty at the time they have to submit bids to CMS about some key issues such as when new drugs will enter the market, both brand-name and generics. Contracts with drug manufacturers about the amount of rebates plan sponsors can expect may not be in place when bids are submitted. And there may be uncertainty about the number of low-income-subsidy enrollees their plans will have.

MS. SUZUKI: So while our interviews with plan actuaries suggest there may be uncertainties that could lead to patterns that we see in plan payments, the persistence of these patterns, rather than randomness that we may expect to see with uncertainties, leads us to ask whether there may also be financial advantages to bidding in certain ways.

We'll consider two potential approaches to bidding. The first is focused on having a competitive premium.

As you saw in an earlier slide, the covered benefit is much more generous above the catastrophic limit than below. The benefit covers 95 percent of the spending above the catastrophic limit, while the benefit covers less than 75 percent, on average, below the catastrophic limit.

What that means is, for a given amount of

spending, say $100 in total benefit per enrollee per month, a higher share of that in the catastrophic phase means more covered benefits and, therefore, a higher premium for the enrollees.

So one approach might be for plans to make their best estimate of total spending per enrollee, but to underestimate the catastrophic spending and overestimate the rest of the benefit, but not high enough to trigger a risk corridor payment. This approach could provide several financial advantages:

First, the plan can keep its premium competitive by underestimating the catastrophic spending because Medicare's direct subsidy will be larger than it would otherwise be, and it offsets the increase in the premium from overestimating the rest of the benefit.

Second, because 80 percent of the catastrophic spending is paid for by Medicare in individual reinsurance, so even if a plan were to underestimate the amount, the plan gets 80 percent of it back at reconciliation.

Third, because plans are 100 percent at risk within the initial risk corridor threshold, if the amount of overestimate doesn't exceed that threshold, the plan gets to

keep all of the "excess" profits, which are in addition to those already built into the bid.

One downside may be the lower cash flow due to lower prospective reinsurance payments. However, because the plan has overestimated the amount of spending for the rest of the benefit, some or all of that will likely be offset by the higher direct subsidy payments.

The second approach is focused on having higher profits.

Again, the plan would underestimate catastrophic spending and overestimate the rest of the benefit, but this time the amount it overestimates the rest of its bid is high enough to trigger a risk corridor payment. So the actual costs are way below the bid. This approach could provide larger financial advantage compared to the first approach.

Just like in the first approach, the plan gets most of the cost overruns back for the catastrophic spending at reconciliation through additional reinsurance from Medicare.

And similar to the first approach, the plan gets to keep the excess profits. However, because the amount is high enough to exceed the initial threshold, the plan must

pay a portion of it back to Medicare. Even so, the excess profits the plan gets to keep under this scenario would be larger than the profits under the first approach.

There are downsides to this approach.

The premium would be less competitive than had the plan correctly estimated the benefit spending, and this has some risk, as beneficiaries can see this readily. It can also affect whether a plan qualifies as an LIS benchmark plan.

Another downside is the lower cash flow due to the lower prospective reinsurance payments. However, most or all of that will likely be offset by the higher payments received for the plan-covered portion of the benefit.

So here's a numeric example to illustrate the potential approaches that I just described. Here I'm using a simplified benefit that we described in the mailing materials, which is different from the real Part D benefit.

In this example, we assume that the plan gets the total spending right in their bid. This is similar to the first approach. We assume that the amount of overestimate for spending below the catastrophic limit exactly offsets the amount of underestimate above the catastrophic limit.

The first column shows the plan bid for an average enrollee. The plan is at risk for $60. The plan expects $40 in reinsurance; that's the 80 percent above the catastrophic limit. The plan expects total covered benefits to be $100 per enrollee per month, of which $25.50 is collected from enrollees in monthly premiums.

The actual cost is shown in the second column. The bid for the plan-covered portion of the benefit was higher than the actual cost of $54. That is, the plan overestimated the spending for that portion of the benefit by $6.

The amount in the bid for the expected reinsurance was lower than the actual cost of $48. That is, the plan underestimated the spending for reinsurance by $8.

Notice that the total covered benefit is higher, $102 instead of the $100 that was in the bid. This is because the Part D benefit is more generous above the catastrophic limit than below, so a higher amount in the catastrophic phase, for a given amount of spending, results in a higher portion of covered benefits.

Another thing to note is that although enrollees paid $25.50 per month in premiums, that should have been

$26, but because $8 of the $48 spent for reinsurance was not included in the bid, the premium didn't reflect this extra benefit spending. So the strategy helped keep the premium low.

At reconciliation, the plan recoups the $8. In our simple example, we assume that the extra profit, or the $6, does not trigger a risk corridor payment, and the plan gets to keep the full amount.

Although individual reinsurance and risk corridors that we focused on in this presentation may only be part of the story, the hypothetical examples provide insights into how Part D's risk-sharing arrangements may affect the plans' bids.

The findings suggest that there may be changes to the risk-sharing arrangements that may better align plan incentives with those of Medicare. However, because changes to the risk-sharing arrangements may have other unintended effects, they will need to be combined with other policies to balance the competing goals for the program.

Potential policy approaches include increasing plans' risk from 15 percent to a higher amount for spending above the catastrophic threshold and/or a full or partial

provision of reinsurance by private reinsurers.

We may also want to consider changes to risk corridors. And because changes to risk-sharing arrangements could affect the plans' risk for enrolling individuals with an LIS due to their tendency to incur higher costs, policies that change the current risk-sharing arrangements would need to be combined with modifications to policies surrounding the low-income subsidy.

Our next step is, in April, we will report on what we learn from talking to private reinsurers about a private provision of reinsurance in Part D. We will also conduct additional analysis on reinsurance and risk corridors.

For the next cycle, we plan to turn to potential policy options for changing the risk-sharing arrangements and their implications for the beneficiaries, plan sponsors, and Medicare. We may want to revisit our recommendation on LIS cost sharing from 2012 as one of the policy options focused on the low-income subsidy.

MR. HACKBARTH: Thank you. This is really interesting and important work.

Could I just ask you for one additional piece of information here. So, you laid out on 12 and 13 two

different ways that a plan might think about approaching this. A critical question, I would think, in choosing between these two strategies is if you go for the higher profit approach, what is the effect on enrollment?

And, I have two different pieces of information in my head. One is, generally speaking, beneficiaries have been pretty sensitive to price. On the other hand, there is some inertia in the market. Once beneficiaries choose, they tend to stay with a plan.

And, so, in choosing between the alternative strategies you have laid out here, it would be important to figure out how you take into account price sensitivity, but also inertia. So, just tell me some more about that piece of the picture.

MS. SUZUKI: So, we've seen, roughly, 12 to 14 percent of beneficiaries switch in a given year, and I think Jack had some research showing that premiums were one of the main factors. But, we also found that people were focused on copays, not just premiums. People who switch plans, in their analysis, tended to have lower cost sharing, out-of-pocket spending, after switching plans, even though their number of prescriptions taken, utilization, did not change

or even increase in some cases.

MR. HACKBARTH: Mm-hmm.

DR. SCHMIDT: I'd also add, you know, these are large insurers offering many different plans, often, in many different parts of the country, and they come in with different strategies, right. Maybe they have a basic plan that's competing for low-income subsidy enrollees and they want to maintain that, so they might be a little more sensitive to premiums and might be more oriented towards the first approach.

MR. HACKBARTH: Mm-hmm.

DR. SCHMIDT: There are others where maybe there's less turnover, they've had pretty consistent membership, and people -- their enrollees maybe seem a little bit less sensitive to price and premiums, so they might use a different approach.

MR. HACKBARTH: So, empirically, we see plans pursuing both types of strategies here.

DR. MILLER: Right, and that's what I would emphasize. In the first instance, it may not be that a plan's tactic is to try and draw more profit. It may be that if you have to put together a bid, you're trying to be

competitive and you're trying to put a premium out there, and I know the copayment, Shinobu, you had another signal.

The other way to think about this is, well, it's a little bit complex. You can do the math within that set of guidelines to hedge yourself a little bit by drawing a little more reinsurance out of it. And, so, in some ways, if you're not playing for the higher profit, it's just how you structure the bid. You're structuring your risk a little bit more carefully and you could end up a bit ahead because of that.

The other thing which I think was implicit in your point, Rachel, is if you do want to play the other strategy and it does result in a higher premium, and so you're running that risk, we're still talking about premiums that are in the $30 range. And, so, even though it might be a larger percentage increase, and we tend to look at them that way, to the beneficiary, how much of a signal that is, I think, is still a question, when it's a few dollars' shift, and across a large insurer, a few dollars can matter in terms of the revenue that they draw and maybe not move the beneficiary.

But, I do think it may be even in the first

strategy, where you're not trying to leverage more profit, there is a way to structure the bid that pulls a little more in, hedges your risk a bit.

MR. HACKBARTH: So, clarifying questions. Jack.

DR. HOADLEY: I just wanted to follow up on your comment. I think Rachel hit a pretty important point. The plan sponsors, who are typically offering two or three different products just on the PDP side, let alone what they might be doing on the Medicare Advantage side, will often have very different strategies, and so -- you know, if they have a new product, they may be coming in, trying to get a low premium because they want to pick up a bunch of new customers who are new beneficiaries entering the market for the first time who are probably price sensitive, may have relatively low drug needs, looking for the cheap plan, and it gets kind of tied up with risk selection a little bit, too, so they get a healthier mix.

And then their older product, it may have people that have aged in and become more expensive, but they're sticky. They don't tend to switch. Then you can be less premium sensitive with those products, and you see some of those sponsors, by looking at the results, seem to be taking

very much of those two different approaches for two different products.

MR. HACKBARTH: Yeah. Interesting.

Rita, and then Dave.

DR. REDBERG: I was just wondering if you have any more recent data on how many beneficiaries hit the cap, because you gave us in 2012 it was two million, but it seems like with what we've been talking about, prices of drugs have gone up and a lot more people are going to be hitting that cap.

My other question, I don't know if it's clarifying, is can we look at implications if the cap was changed to make it higher catastrophic.

DR. SCHMIDT: Well, unfortunately, the claims data that we get, 2012 is the latest that we have at the moment. But, hopefully, we'll get 2013 soon, so we can at least give you a little bit more of an update there.

In terms of changing the cap, I mean, I guess we could play around and come back to you maybe with different numbers of -- counts of people who would hit the cap at different levels, if that would be helpful.

DR. REDBERG: I would be interested in the spend

implications --

DR. SCHMIDT: Right.

DR. REDBERG: -- of that for Medicare.

DR. HOADLEY: I mean, the cap does go up with a -- based on drug spending increases year to year, and actually, for 2016, the new notice suggests that there will be a larger than -- a significantly larger than normal increase in the cap, as well as some of the other --

DR. REDBERG: Do we know what that will be?

DR. HOADLEY: It's about a ten percent increase? Yeah, about a ten percent increase. I don't remember the broad number, but --

DR. NERENZ: Just a very small semantic question. Slide 14, lower left. The word "extra" -- I would have thought that the difference between 60 and 54 is sort of base or core or some kind of profit. The word "extra" implies that this is one thing, but then there's other profit or more basic profit. What's the other?

MS. SUZUKI: The other profit is built into the plan bid. So, the $60 already reflected some built-in profit --

DR. REDBERG: As part of their --

DR. NERENZ: And that's not the difference between 60 and 54?

DR. SCHMIDT: No. It's part of the administrative expense. You know, there's administrative cost, but they also build in some margin into that. When CMS calculates things like the risk corridors, they're not even looking at that. I mean, they review that during the process of reviewing bids prospectively, but that's in addition to this calculation.

DR. NERENZ: So, that's what I wanted to clarify. It's in addition to the difference between 60 and 54.

DR. BAICKER: So, just to make sure I understand the different components of plans' bids, on Slide 9 and on Slide 14 -- maybe on Slide 9 is a good place to look at it. Individual reinsurance, we're saying that plans underbid on catastrophic spending, meaning catastrophic spending is bigger than the bid would reflect and so they get a net payment, and they overbid on the rest of covered benefits, meaning they have to make a net payment back. But, there's only one bid, correct, that harmonizes these two. You know, they only have one parameter to play with, correct?

DR. SCHMIDT: When they bid, they come in with

what their expectation is of reinsurance, so --

DR. BAICKER: But, that's non-binding in any way, right? I mean, they -- can they separately bid on not-reinsured and reinsured? Those don't move independently.

DR. SCHMIDT: They are related to one another. They come in with an estimate of total spending per member per month and an estimate of that, what they expect the individual reinsurance payment to be. So, those two are connected.

DR. BAICKER: Right. So, what I'm trying to separate out, there's really only one degree of freedom for them in that they can -- they come in with a total bid that happens to be composed of multiple components --

DR. SCHMIDT: Mm-hmm.

DR. BAICKER: -- but it's not as though these two levers can move independently and they are getting independent -- enrollment is based on just the one bid, you know, enrollees just see the one number, and the one number then dictates what -- whether they're above or below the benchmark, et cetera. It's not as though they get to decide two separate things that then have separate ramifications for what they're getting paid back. They have to add them

together and just produce the one number.

MS. SUZUKI: Right. And, I think you're right. They're related. And, the way we thought about it in the simplified model is where they draw the line of catastrophic versus non-catastrophic is where your degree of freedom is --

DR. BAICKER: But that line is not meaningful --

DR. MILLER: See, and what I was going to say is we might agree with you, depending what you think that one degree of freedom is. I think what we're saying is, there's a big. You can move around, whether you over or underestimate the basic benefit or reinsurance. I think I could interpret your comment as, no, there's only one degree of freedom, the total bid --

DR. BAICKER: And, in some sense, it doesn't matter what you're calling that line. If my bid is 100, I could say, well, in my mind, it's 50 and 50, or in my mind, it's 60 and 40 --

DR. MILLER: [Off microphone.] Well, indeed, in the bid, it will also say that.

DR. BAICKER: But, does it matter --

MS. SUZUKI: It does --

DR. BAICKER: Is there any import to where you've drawn that line in the bid?

MS. SUZUKI: It affects your premium, because the way the benefit works is it's much more generous above the catastrophic. And, so, how much you put in the catastrophic can affect the beneficiary premium.

DR. SCHMIDT: It might also be helpful to say, you know, the overall government subsidy is 74.5 percent of the average --

DR. BAICKER: Sorry.

DR. SCHMIDT: The overall government subsidy is 74.5 percent of the average, and when the bids come in, CMS is looking at how much of that, overall, is the expectation of reinsurance. And, they take that percentage off of the 74.5 percent and the remainder is the direct subsidy that offsets -- that lowers the premiums for everybody. So, those pieces of subsidy are related to one another. I don't know if that helps with your question or not.

DR. NERENZ: Well, just to clarify, does the bid have two distinct, explicit components?

MR. HACKBARTH: [Off microphone.] Yes.

DR. BAICKER: And one component affects the

beneficiaries. Only one component affects what the beneficiaries pay, or both together?

DR. SCHMIDT: Both together.

DR. BAICKER: And, so, then, what -- only one component --

DR. HOADLEY: They affect the beneficiary at different percentage levels, and they affect the Federal subsidy at different percentage levels. So, it's affecting both the interim payments that the -- I mean, the interim payments that the plan is going to get for reinsurance, but more importantly, it affects that overall calculation of how much the beneficiary owes.

DR. BAICKER: Right, because the truing up at the end that's based on actual -- what is actually reinsured --

DR. HOADLEY: Right.

DR. BAICKER: -- that's not affected by what you thought the reinsurance would be. It's only affected by what actual spending patterns were in excess of the maximum threshold.

DR. HOADLEY: Where it affects what you end up getting, though, is the interplay that they went through in this sample case between the reinsurance payments and then

the risk corridors. They help to affect whether you hit the risk corridors, and they affect a lot of the math on the way. But, you're right. The amount of money they get in the end, before the risk corridors fit in, is based on actual results. But, the bid that leads to a premium, if you would guess the split right, you would have gotten a different premium. If you guessed the split in different ways, you'd get different premiums out of it.

DR. BAICKER: Ahh. So, they do have two degrees of freedom --

DR. HOADLEY: Freedom.

DR. BAICKER: There's the total bid. The split matters because the estimated portion of the reinsurance affects --

DR. HOADLEY: The premium --

DR. BAICKER: -- the premium --

DR. SCHMIDT: The premium calculation.

DR. BAICKER: -- differently --

DR. SCHMIDT: Right. That was the --

DR. BAICKER: -- from the estimated --

DR. HOADLEY: Yeah.

DR. BAICKER: -- portion of the other.

DR. SCHMIDT: Right. So, that's the 74.5 percent gets reduced by the amount of the expected reinsurance, and that remaining subsidy is what lowers the premium for all the enrollees.

DR. BAICKER: So, both the mix and the total level matter in terms of what beneficiaries then see when they're making their decisions. So, that's the extra opportunity for strategy in trying to attract enrollees or be in an LIS plan, et cetera. But, then, there is still financial import of the total guess as well as the part that the beneficiaries see.

Well, I hope that clarified for everyone.

[Laughter.]

DR. MILLER: And, the only thing, and since you're settled, I hate to say this, but --

[Laughter.]

DR. MILLER: -- the only thing I would have said differently is when you entered and said the corridor, which I think your statements were true in and of themselves, you can still, depending on how you calculate the reinsurance versus the direct subsidy part, even if you're not -- even if in an example you don't hit the corridor, you can

structure the bid to come out a couple of dollars ahead. And, I just want to make sure that you don't have to bring the corridor into this discussion for these statements to be true.

Okay. So you are settled. All right.

MR. HACKBARTH: Clarifying questions. Bill.

MR. GRADISON: I was glad to see you're going to bring us some information on private reinsurers, or the possibility of them.

These plans did not exist in nature before this was put on the books, and, therefore, there was no track record, and, therefore, there not only were no insurers offering coverage, there were no reinsurers backing them up. The level of reinsurance, its availability and its price, I presume, have some relationship to the reserve capacity, the reserves of the plans themselves. And, I just wanted to -- it speaks for itself, but I just hope, as you get into this and talking to the reinsurers, you can get maybe a better sense of how they read this. I suppose if the plan is offered by a very large insurance company, that the total reserves of that company would stand behind the segments of different types of insurance, including Part D.

But, in any event, I'm glad to know you're going to be taking a look at this. Thank you.

MR. HACKBARTH: Any other clarifying questions?

Round two. Jack, do you want to go first.

DR. HOADLEY: Sure. So, this is really helpful in working through, and I learned some stuff from the way you structured this analysis. I really appreciate that.

You know, I do think that what we've identified is some issues in both how the overall structure of the risk protections work, but particularly some additional complexities in how it affects bidding. So, I mean, we've talked in the past about whether all of the things that were done in year one to kind of make sure there'd be plan entry, and we had the discussion some meetings ago about back on the first day, we weren't even sure people would come to the table, and so, clearly, Congress was aggressive in saying, let's put a lot of protection in. Let's just make sure that there's -- we keep the barriers to entry low. They accomplished that. Lots of plans came in. Arguably, too many plans came in.

And, the risk corridors actually were by design, became wider after a couple of years, and there's statutory

authority to further widen them that the Secretary has never taken advantage of. I mean, that's one question.

And, I think what I come to after I look at this, I mean, the whole combination of this system, including the sort of bidding strategy, is some potential to distort bidding. Some of these cases, it actually works to the short-term benefit, at least, of the beneficiaries if it lowers premiums, maybe to the adverse effect on the taxpayer on the program as a whole. Whether it benefits beneficiaries over the long haul, I think, is less obvious, because who knows what goes on if they come in cheap and then raise prices later.

It also, as we've discussed before, has an effect on the ability of plans or the incentives for plans to manage expensive drugs, manage drug spend in general, particularly expensive drugs. I was one of the people that -- I did a blog last summer saying Sovaldi could easily lead to an increase in the premiums for Part D, and then people have come back and said, well, we didn't see a big increase in premiums for 2015 in Part D, and that was really my not thinking through enough of the sort of reinsurance impact. It seems pretty clear from the kinds of examples here that

you can afford to face an expensive drug like Sovaldi coming on the market, or the newer Hep C drugs that have come on since then, coming on the market and absorb that impact because the government picks up most of the difference.

So, all of that kind of leads me to think that there is a track towards some policy choices to potentially reduce the reinsurance, make plans at risk for something higher than the 15 percent, maybe keep the risk corridors as they're right now not really providing protection for the kinds of Sovaldi examples, but if reinsurance were reduced, then they would potentially be there to cover that, plus, in the short term, it's actually protecting the government from plans having excess profits, and so that was the other purpose of the risk corridors.

But, that we might also want to think, if we're doing those kinds of things, you talk about sort of the corollary effects, is also think about is this an opportunity to sort of work a little bit with the catastrophic protection for the beneficiary. So, right now, the beneficiary has no fully out-of-pocket limit -- now, that's true, of course, in other parts of Medicare, as well -- continues to pay five percent of the cost throughout the

year. The beneficiary also faces a very front-loaded cost structure, so the cost for somebody using very expensive drugs is loaded up front and it's a disincentive to start treatment, even though later on, if they start it and they pay that up front cost, they'll do better.

But, if we're trying to think about how to do this, it might be a good opportunity to think about some ways to rejigger the catastrophic protections for the beneficiaries at the same time, and that -- I can't quite think through all the ways those interact, and even putting the LIS piece into it. But, I think that's the kind of route I'd like to see us really think about, is reduction in the reinsurance by the government, but more of the burden on the plans, and think about some additional protection for the beneficiaries while we're doing it.

MR. HACKBARTH: Round 2. Rita.

DR. REDBERG: I really just agree with what Jack said and just want to emphasize what I said earlier because I think sovaldi is clearly very expensive, and there are, as I said, a few new drugs that I think will be coming on the market this year that will be very expensive and have even more -- because they will be for chronic illnesses and

chronic diseases have even more cost implications, so that the $300 billion I think that we currently spend now in drugs, people are predicting these drugs are going to add hundreds of billions of dollars to our overall drug spend.

So I would like to see Medicare not be on the hook, as we are, for that catastrophic spend because I think it's going to be -- blow the budget.

MS. UCCELLO: Yes. I agree with the comments so far, and I just want to say how great a chapter this was and how much I appreciated the example. I think that was really kind of critical to kind of helping me put all the pieces together, so I really appreciate that.

In particular, kind of the light bulb went off above my head with respect to the premium and the reinsurance part, so I think I finally get what you've been trying to tell me for a year or two.

So nothing more to add but just thank you.

DR. MILLER: [Speaking off microphone.]

MR. HACKBARTH: Round 2. Jon.

DR. CHRISTIANSON: So I'm not sure -- I want to first say something related to Bill Gradison's comments. When you're talking about doing interviews with actuary --

not actuaries -- reinsurers -- so if I understand the market right for these plans, a large share of the market is large insurance companies, like UnitedHealthcare, that you would expect, if you were to pull out the government-sponsored reinsurance, would reinsure themselves.

DR. SCHMIDT: I think that's correct.

DR. CHRISTIANSON: So then there are some small players in the market. So is the purpose of the interviews to try to figure out whether the reinsurance market out there would be available to the small insurers at a reasonable price? Is that what you are doing?

DR. SCHMIDT: Yeah. And just to understand if they were to offer a product to Part D insurers, what structure would it take. In our preliminary conversations -- I'll be honest -- we haven't had a good grasp on what premiums for that kind of insurance might cost.

DR. CHRISTIANSON: Yeah.

DR. SCHMIDT: Those kinds of questions, yes.

DR. CHRISTIANSON: Yeah. And then to follow up Rita's comment, if we were to eliminate the government-sponsored reinsurance, my understanding is that it wouldn't take Medicare -- did you say take them off the hook? Yeah.

Because then the cost of the reinsurance that the companies bought for themselves from the market would be built into their bid anyway, right?

DR. SCHMIDT: That's correct.

DR. CHRISTIANSON: And we would pay 75 percent of that cost instead of 80 percent or something?

DR. SCHMIDT: Right.

DR. CHRISTIANSON: But anyway, the cost is going to show up one way or the other. We are not going to reduce Medicare spending by that amount. Is that right?

DR. SCHMIDT: That's right, but there may be some incentive that a different amount of government reinsurance provides to the plan sponsors in their negotiations for drug prices.

DR. CHRISTIANSON: Right. That's what we're really talking about here is changing the incentives on the margin.

MR. HACKBARTH: To me, this analysis calls into question -- and I mean, just a question, not an answer -- whether reinsurance and risk quarters are needed in Part D. Then I think about Part D versus Medicare Advantage, where the government doesn't provide reinsurance or risk

corridors, and I think that the variability in the risk faced by Medicare Advantage Plans is greater than the risk faced by Part D plans.

So what's the policy rationale for continuing these features for Part D when they're not in Medicare Advantage? They may have had a rationale for the reasons Jack describes at the beginning of Part D to get people into the program, get it up and running. I don't see the rationale at this point, particularly given the sort of analysis that you've done.

Help me. Be the devil's advocate and say, "Here's why you would do it in Part D when you don't do it in Medicare Advantage.

DR. SCHMIDT: I can just tell you some of the comments we heard from the actuaries in conversations, that the existence of the risk corridors allowed them to maybe experiment a bit more with benefit design, to try and be innovative. We heard those kinds of things. It was a help to new entries, new insurers that wanted to enter the market. Those were the kinds of responses we got.

MR. HACKBARTH: The consistency in the level and direction of the risk corridor payments that they're always

paying back and the same amount year after year, to me -- I don't want to say anything anti-actuary, but I thought actuaries were supposed to base what they say on data, and the data seems inconsistent with what they are telling you.

DR. MILLER: Well, this is getting awkward.

[Laughter.]

DR. SCHMIDT: Cori, do you want to speak for the actuaries?

MS. UCCELLO: Well, I'm not going to disagree on the risk corridor.

MR. HACKBARTH: Yeah.

MS. UCCELLO: But do you want to hear the reinsurance part?

MR. HACKBARTH: I'm being more emphatic than I should be, but I'm trying to provoke a response. Tell me why I'm wrong, somebody.

DR. BAICKER: Well, there is this -- I don't read from any of this that actuaries haven't gotten it exactly right. I understand from all of this that there's a lot of strategy in how you structure the bid and that there could be a strategic reason to systematically draw that line someplace different, which doesn't mean they don't have good

forecasting models, necessarily.

And your point about variability, I thought it was interesting to see the Part D versus Part A and B variation that was in the text box in the chapter, and it looks like while the variation has crept up in Part D, it still doesn't exceed what you'd see in Part A and B, which isn't exactly the MA. But my interpretation is that it is no more difficult to take into account individual variation.

And then the question goes back to my perennial solve risk adjustment. Is it that the risk adjustment is really bad in Part D and so you need this backstop to avoid cream skimming and trying not to enroll the most expensive enrollees? And I also don't think we've come up with any evidence that the risk adjustment is less adequate in Part D than it is elsewhere, but that seems informative too.

DR. CHRISTIANSON: I like the parallel with Medicare Advantage in another way that Jack raised, which I think it was in the ACA that we now have a maximum out-of-pocket limit for beneficiaries that enroll in Medicare Advantage plans.

MR. HACKBARTH: Right.

DR. CHRISTIANSON: That's one of the advantages of

doing that versus staying in fee-for-service Medicare.

We don't have that, as you pointed out, in the Part D plan, and so I really do think that's something we need to -- I'm agreeing with you. I think we need to look at that, and I think it's arguably feasible because of the experience with Part C.

MR. HACKBARTH: Are there other people who want to react to my tirade? Do you want to react to my tirade?

DR. CROSSON: Just one quick follow-up. I'm not sure it's a reaction. I mean, it was similar to what I was thinking myself as I read through this, which is when we do our work around payment adequacy, we often ask the question about access, and then to the extent we can, we look at margins. If there is another parallel here, it's -- well, the purpose, as Jack said, of creating this three-tier risk management structure, including risk adjustment, was to make sure that plans came in, and then make sure, to some reasonable degree, that they didn't suffer catastrophic losses and therefore leave.

So if we were to think about this in the way that we think about payment adequacy questions, we would ask, "Does the current structure provide access to beneficiaries

to coverage?" and I think the answer from the text is yes, it does, and perhaps even more than is needed.

What do we think about the profitability of this, and are there mechanisms that we can use, MedPAC can recommend or that Medicare can use, to make sure that the profitability is within reasonable bounds? It sounds to me like at least with respect to the individual reinsurance mechanism and the way that it plays out, it may in fact be contributing to a level of profitability, which is beyond what we would think is reasonable when we were looking at other areas of Medicare, benefits in Medicare coverage.

I am not sure that I completely understand, and it seems like we have to spend some real some understanding what would happen if you changed the reinsurance lever or you changed the risk corridor lever and whether that actually resulted in a real benefit to the program and didn't adversely affect beneficiaries, but I would favor doing that sort of analysis.

MR. HACKBARTH: Okay. Round 2 comments. Any subject people want to raise? Jack.

DR. HOADLEY: Just one quick follow-up, partly to this last dialogue.

You're right that there is a big difference in Part C versus Part D, and obviously, history is part of that. You can make the argument, I think -- and I don't know how convincing it is -- that the entry -- and this is one of the things the actuarial interviews brought up is that the entry of new product and the long lead time when they have to submit their bids versus when these products might get approved and not knowing launch prices is a kind of uncertainty that you don't have a real equivalent for in Part C, at least not in a sort of magnitude of how a couple of products could really affect an amount in the market.

MR. HACKBARTH: More about that, Jack? I don't understand why it's of greater magnitude in Part D than C.

DR. HOADLEY: If hep C drugs come in and represent 3, 4, 5 percent of drug spend, as they seem to do, and that was not something you were aware when you had to make your bid was going to happen, that's a 3 to 5 percent increase. And I'm hard-pressed to think how a new innovation in surgery or something like that would be as quick and as large as a share of overall spending. That's the argument. I'm not completely convinced on that, but I think that's the case I would try to make back.

My statement initially was, potentially, do some fairly significant change to reinsurance, leave the risk corridors alone, and maybe you would then look to reduce those or eliminate those when you make sure that you -- so it could be a transition even that as you make a change on one of the piece, one of the R's, you don't immediately make a change on a second R until you've made sure that's only going to have the amount of effect you expect. Then you could go on and attack that and get it back to the point where -- maybe to get your analogy, get it back to sort of the Part C level where you do risk adjustment but not the others.

MR. HACKBARTH: I now understand your point about why Part D may be different than Part C, although to me, that's what private reinsurances do. It doesn't amount to a case for government reinsurance.

MS. UCCELLO: Except for the -- aside from saying that the risk adjustor is fine, again, it's fine, I think, in part because there's a cap on it, because of the reinsurance, but this idea of reinsurance, in effect, turbocharging the risk adjustment factor, so that you're compensating the plans appropriately, so they're not

avoiding people. And prescription drugs are more predictable, and so perhaps the variability, the predictable variability with drugs is greater than the predicted kind of variability for medical spending overall, and so that could be part of the reason to have the reinsurance.

DR. BAICKER: And the magnitude of the risk that Jack brings up is really important in that it may be hard to get reinsurance for something that's a correlated risk where a whole sector could move a bunch. If there was suddenly a new drug that doubled everybody's cost, that's hard to reinsure against. Doubled is very different from 2 or 3 percent, which is still -- it's a huge share to be represented by one innovation, but the question is, is it big enough to interview with private reinsurance markets? I have to think it's not that big relative to buildings falling down and things like that, but I don't know.

DR. HOADLEY: I mean, there's another side of trying to look at this that -- how do you try to think about these market entry kinds of factors? So one of the responses plans made to the hep C drugs coming along is to apply very strict utilization management. Now, that could be a good thing, or it could be something that really limits

access, and so as we think about the tradeoffs, we want to think if we ratchet back too far in one way, will the response be to do things that could have adverse impact on access or appropriate management.

We can come up with -- you know, Rita's example of some of the new drugs coming on may turn out to be drugs that are very expensive, looked very useful, but in fact don't have very good results. Hep C, so far it looks like it has pretty good clinical results, and the argument for using it is pretty high. But we've certainly got a lot of other examples of drugs that come on that are expensive. They get a lot of use, but their efficacy is not so good. And so how do we get the right incentives on the plans to manage in a way that will be clinically appropriate for beneficiaries, preserve appropriate access, but also pay attention to cost?

DR. REDBERG: On a technical point of hep C, what it looked very good on was the sustained virologic rate, but what we hope it really does is reduce cirrhosis of hepatocellular cancer, and that, we don't have data on, so --

DR. HOADLEY: Even that one has question.

DR. REDBERG: That's all models. Yeah.

MR. HACKBARTH: I think Carlos came to correct something I said.

MR. ZARABOZO: No, no. It's not a correction. It's just that in the case of Part C and Medicare Advantage, there is a statutory provision that says if there is a national coverage determination that has a significant -- I think it also says significant financial impact -- that occurs in the middle of the year, that it was unanticipated in the MA bids, the government is at risk. The plans are not at risk for the coverage of that particular -- those services.

DR. MILLER: The linkage is to a national coverage decision?

MR. ZARABOZO: Right.

DR. MILLER: Yeah.

DR. CHRISTIANSON: So just to make sure I understand what's going on, if I enroll in a Medicare Advantage plan, Part C plan, that has Part D drug coverage, do my drug expenditures in that plan run up against the -- are counted against the out-of-pocket maximum?

MR. ZARABOZO: No. That's a separate --

DR. CHRISTIANSON: No, they aren't. So it doesn't matter whether you enroll in a Medicare Advantage plan or Part D. Your drug expenditures still have no out-of-pocket max.

MR. ZARABOZO: Yeah. It's all under D. It's the same rule as under D.

MR. HACKBARTH: Kathy.

MS. BUTO: Jack, I wonder if you could just elaborate a little bit. I am still not getting why the risk -- it feels like belt and suspenders to me, risk corridors and the reinsurance. So why at a minimum, we wouldn't want to -- well, I think we probably will consider whether we think they're still needed, because they were originally designed to attract and make sort of safe, the environment for Part D plans. So I'm just curious why you think you would still need to have those.

DR. HOADLEY: I mean, I think you could easily make the case that you wouldn't. Part of my case is just to say let's take things on a more gradual track and make sure you don't shock the system so far that you've caused some unexpected events. The fact that the government is the beneficiary of the risk corridors so consistently also makes

-- if we took away the risk corridors, they would actually be scored as a cost to the government right now, I would assume. So being done in combination with other things, who knows how that would play out? But, I mean, I think that is a factor in the way I laid that out.

But part of it is just, yeah, maybe we do want to end up at a point where risk adjustment is enough or a much more modest risk corridor that is only kind of addressing these very large shocks to the system, much wider kind of risk corridor, but maybe we don't want to make all that change in one year.

MR. HACKBARTH: Other comments, questions?

[No response.]

MR. HACKBARTH: Okay. Good work.

We will now have our public comment period.

[No response.]

MR. HACKBARTH: Seeing nobody move towards the microphone, we are adjourned. See you next time. Thank you.

[Whereupon, at 11:01 a.m., the meeting was adjourned.]