MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Thursday, November 5, 2015
10:13 a.m.

COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[10:13 a.m.]

DR. CROSSON: Okay. I think we're ready to begin the morning session.

We are going to go back over our work on sharing risk in the Medicare Part D program. This is part of our ongoing work on the cost of pharmaceuticals. Even though this is not directly focused on the pharmaceutical industry itself, it is in fact focused on the plans. I think our feeling in the past has been that there could be some improvements in the market dynamics between the plans and the suppliers and manufacturers of drugs, and so we're going to be focusing in here on the question of whether or not the current risk mitigation mechanisms, which were put in place when the Part D bill was passed, are what we want today or whether or not there should be some changes made.

We're going to have Rachel and Shinobu take us through this part of the deliberation, and my hope is that at the end of this session, we have a clearer idea and perhaps a more specific idea about where the Commission would like us to go.

MS. SUZUKI: Good morning. Today we will continue

our discussion from the last cycle about whether changes to Part D's risk-sharing arrangements might better serve the program by encouraging plans to manage drug costs more effectively while ensuring access.

In this presentation, we'll quickly review some of the main points from our June 2015 chapter, going over patterns of Medicare's payments to plans we've observed through 2013.

Next, we will present new data for 2014 and discuss effects of drug prices on program spending.

Then we begin our discussion of potential policy changes. The focus here will be on providing plans with a stronger incentive to manage drug spending through increased risk exposure, while at the same time also providing them with more tools and flexibility to manage spending.

We will end the presentation by laying out potential policy options. We will be looking for your guidance on the next steps.

This slide is a reminder of the ways in which Medicare shares risk with private plans. The direct subsidy is the capitated payments for the portion of the

benefit in which the plan sponsors bear insurance risk. Because of this, they have an incentive to manage the drug spending and use, and keep the premiums low.

The direct subsidy is risk adjusted to offset the incentives for plan sponsors to avoid higher cost beneficiaries.

Medicare pays individual reinsurance for each plan enrollee with drug spending above Part D's catastrophic threshold. This is essentially an open-ended payment with Medicare covering 80 percent of the cost above the catastrophic threshold. While this counters plans' incentive to avoid high-cost beneficiaries, it's the one area where cost has been growing rapidly.

Finally, Part D has risk corridors to protect against unanticipated costs. The corridors are symmetric so that they limit plans' losses and profits.

As we consider changes to Part D's risk-sharing arrangement, it's important to keep in mind how these changes interact with Part D's low-income subsidy.

Here is a quick overview of the subsidy. It's available to beneficiaries at or below 150 percent of the poverty and provides premium and cost-sharing subsidies.

The law sets a nominal copay amount, and they do not have a coverage gap.

In 2013, 12.4 million, or about one-third of beneficiaries, received the low-income subsidy.

Most are enrolled in stand-alone PDPs.

Those who receive the low-income subsidy tend to have higher spending compared to other beneficiaries. In 2013, spending averaged $377 per month among the low-income subsidy beneficiaries compared with $179 per month for non-LIS beneficiaries.

In addition to the low-income subsidy, sizable portions of the direct subsidy and reinsurance are also for this population. When combined, spending in 2013 for low-income subsidy enrollees totaled about two-thirds of total program spending.

This table shows the per capita spending for basic Part D benefits for the 2007-through-2013 period.

Average enrollee premium, shown at the top, has remained relatively stable, particularly during the last four to five years.

The next two rows show that plan sponsors had been less successful at controlling cost growth when they

faced less risk. The amount of spending on direct subsidy has been going down, while the Medicare's payments for reinsurance has grown by nearly 10 percent per year, on average.

This is the subsidy where plans are not at risk, and it's growing much faster than the other spending for which they take risk.

We also observed that prior to 2014, reconciliation payments showed a regular pattern. For the majority of sponsors, Medicare ended up paying out more individual reinsurance money to the plans when they reconciled the payments. The positive amounts in yellow mean Medicare paid the plans; that is, the plan sponsors underestimated how much of their covered benefits would fall in the catastrophic part of the benefit.

The reconciliation data also show that in each year since Part D began, plan sponsors have, in the aggregate, paid Medicare back through risk corridors, shown in green, because sponsors overestimated the rest of the benefit spending.

Just to summarize, at reconciliation, Medicare paid most plans more for reinsurance because they bid too

low on catastrophic spending, and then the plans paid Medicare a portion of the additional profit they made through risk corridors because their bids were too high on the rest of benefit spending.

The growth in Medicare's payments for reinsurance is closely related to the growth in drug prices, and I'll come back to this point shortly.

Over the past year, growth in prices for existing drugs, both generic and brand-name drugs, and high-launch prices for new therapies have become a major concern. The pipeline of potential new therapies increasingly includes biologic agents that tend to have high prices. Many of those high-cost therapies have no therapeutic substitutes, which means that plan sponsors have little leverage to negotiate rebates and discounts with drug manufacturers.

For these drugs, putting more risk on plans may simply translate into higher enrollee cost sharing or premiums because, in many ways for these drugs, plans are price takers. This is why a policy that Rachel will be discussing combines a policy that shifts more risk to plans with policies to give plans more tools and flexibility.

Medicare trustees estimated in their most recent

report that came out in June that reconciled payments would show a different pattern for 2014. In that report, they estimated that they would make more than $13 billion in reconciliation payments to plans, of which $9.9 billion would be additional payments for reinsurance and $2.3 billion would be payments for additional low-income cost-sharing subsidy. Both are much higher than the amounts Medicare's paid out in the past at reconciliation.

The trustees also estimated that Medicare would make aggregate risk-corridor payments to plans to share their 2014 losses.

The report attributed much of this on the use of new hepatitis C therapies that were not fully accounted for in the bids submitted by plan sponsors in the spring of 2013.

While patterns of payments 2014 diverged from the patterns we observed for earlier years, the preliminary data for 2014 reinforces the need to focus on the spending above the out-of-pocket threshold, 80 percent of which currently is picked up by Medicare's individual reinsurance.

In 2013, the characteristics of beneficiaries

with spending high enough to exceed the out-of-pocket threshold are similar to previous years. About 2.9 million, or about 7.6 percent of all Part D enrollees, had spending above the out-of-pocket threshold, and the majority received the low-income subsidy.

There are a few new trends that's worth noting. One is the faster growth in the number of non-LIS enrollees who reach the catastrophic phase of the benefit.

Between 2007 and 2013, the number of non-LIS enrollees grew by 9 percent per year, on average, compared with 2 percent for LIS enrollees.

Another is that those who reach the catastrophic phase of the benefit are accounting for a growing share of spending. They accounted for 40 percent of the total Part D spending before 2011, accounted for 44 percent in 2011 and 47 percent in 2013.

And, finally, that spending growth has been driven primarily by growth in prices. Between 2007 and 2013, spending by or for this population grew by 8.4 percent per year, on average. 6.9 percent was due to price growth, while 1.4 percent was due to volume growth.

Now let's turn to potential policy options. Part

D's risk-sharing provisions were set up before there was a market for stand-alone drug plans. That market is pretty robust today, so it may be time to revise Medicare's risk sharing to reflect current goals for the program. One goal continues to be ensuring that Part D enrollees have good access to appropriate medicines. But given the concerns that Shinobu described, it may be time to encourage plans to better manage the use and spending of enrollees who reach the OOP limit.

In our June report, we discussed how Medicare might give stronger incentives to control spending by making plans shoulder more insurance risk. However, growth in drug prices seems to be playing a big part in spending growth for enrollees who reach the OOP limit, and for some drugs without therapeutic substitutes, plans may not have much bargaining leverage over rebates and prices. So we think it's also important to consider giving plan sponsors more flexibility than they have today in using management tools, which might be a factor in their negotiations. Finally, some commissioners have pointed out that beneficiaries who reach Part D's OOP limit can face a considerable financial burden. However, having some cost

sharing above the OOP limit may provide friction against drug price increases. We'll talk about a way to limit financial exposure using fixed-dollar copays.

DR. SCHMIDT: So now let's turn to potential policy options.

Part D's risk-sharing provisions were set up before there was a market for stand-alone drug plans. That market is pretty robust today, so it may be time to revise Medicare's risk sharing to reflect current goals for the program. One goal continues to be ensuring that Part D enrollees have good access to appropriate medicines, but given the concerns that Shinobu described, it may also be time to encourage plans to better manage the use and spending of enrollees who reach the out-of-pocket limit.

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sponsors more flexibility than they have today in using management tools, which might be a factor in their negotiations.

Finally, some Commissioners have pointed out that beneficiaries who reach Part D's out-of-pocket limit can face considerable financial burden; however, having some cost sharing above the out-of-pocket limit may provide friction against drug price increases. We will talk about a way to limit financial exposure using fixed-dollar copays.

Last spring, we discussed Part D's risk corridors, the arrangement where Medicare shares in plan profits if plans' costs are a lot lower than expected or shares in plan losses if costs are much bigger.

Risk corridors provided training wheels for the new market of stand-alone drug plans, and we questioned whether they were still needed; however, we saw that over the first eight years of Part D, the risk corridors essentially functioned as a limit on plan profits. In the aggregate, plan sponsors earned profits higher than what they already built into their bids, and most plans paid Medicare back some overpayments at reconciliation.

For 2014, we don't yet know whether there's been a shift in that trend. When the Medicare trustees released their report last July, they estimated, as Shinobu told you, that plan sponsors hadn't anticipated the magnitude of spending for new hepatitis C therapies. There was a lot of uncertainty about launch prices and how widely physicians would prescribe these medicines.

So, for 2014, the trustees expected that under Part D's risk corridors, Medicare will pay money to plans to share in their losses. At some point, CMS will come out with the actual results for 2014, so you might want to revisit the issue when there's that additional information.

The June chapter also looked at reducing Medicare's individual reinsurance, which would give plan sponsors stronger incentives to manage benefits. The approach involves keeping Medicare's overall subsidy for Part D the same but providing more of it in the form of capitated payments rather than open-ended reinsurance.

We talked about how the current approach may be giving sponsors a financial incentive to bid in a certain way, so reducing reinsurance but also raising capitated payments might change that.

Now, there could be some offsetting behavioral effects. More risk means that plan sponsors would have greater incentive to bargain hard in their negotiations with manufacturers and pharmacies or to figure out more efficient ways to deliver benefits. But more risk might also mean that some plan sponsors, perhaps especially smaller companies, might need private reinsurance, which would raise their costs.

We point out in the mailing materials that most Part D enrollees today are in plans run by large insurers that may be in a better financial position to take on risk, and many of the same insurers sponsor Medicare Advantage plans that have a much higher average benefit value but don't get reinsurance from Medicare.

Now, if we consider how to go about changing Part D's reinsurance, we could lower it or we could eliminate it altogether. Eliminating Medicare's reinsurance would provide the strongest incentives for plans to manage costs; however, that would also lead to the strongest incentives for plans to avoid high-cost enrollees, many of whom receive the low-income subsidy.

You might also consider giving plans more

flexibility in their use of management tools, including formularies. We need plan sponsors to cover drugs that treat a wide range of conditions, but if a plan can't exclude a drug from its formulary or limit use, it's hard to negotiate over rebates and prices.

Medicare law and regulations have specific rules for Part D that can be very different from how plans run formularies for their commercial business. For example, the law says that plans must cover at least two drugs per therapeutic class. Additionally, Part D plans have to cover all or substantially all drugs in six protected classes.

CMS conducted a review and thought that two of the six classes -- antidepressants and immunosuppressants for transplant rejection -- no longer needed to be protected.

Last year, the Commission was generally supportive of CMS's position in a comment letter because those classes have had a lot of generic entry; however, after receiving public comments, CMS's proposal wasn't implemented.

Another potential area for more flexibility

relates to changes in formularies. If a plan wants to change its formulary in the middle of a benefit year, the plan can make additions without getting approval, but plans have to get CMS's approval before negative changes. For example, if a new specialty drug comes on the market and is in a class that doesn't yet meet the two-drug-per-class requirement, the plan has to cover it, and before a plan can apply prior authorization to the drug, it has to get CMS approval and lay out the criteria the plan would use for prior authorization decisions.

One potential policy change might involve less stringent rules around, for example, permitting more use of prior authorization when a new drug enters the market, especially for drugs launched at very high prices.

Plan sponsors tell us that there are other ways in which their Part D formularies differ from their commercial formularies. For example, they might first fill a 14-day supply for a month's prescription of high-cost drugs with a subsequent fill if the therapy continues, if the patient adheres to the therapy. If a beneficiary gets switched to a different drug or doesn't adhere to the regimen for some reason, that approach helps reduce waste.

In Part D, plans tell us that they have to fill the number-of-day supply as written by the prescriber currently.

In 2012, the Commission recommended that the Congress give the Secretary authority to provide stronger financial incentives for low-income subsidy enrollees to use lower-cost generics when they're available. This was motivated by the observation that while all Part D enrollees were using more generics, LIS enrollees were using noticeably more brand-name drugs than non-LIS enrollees. And LIS cost-sharing amounts are set in law. So one of the key tools plans use to manage spending is not available for this population.

In the time since the Commission made that recommendation, Part D plan sponsors have begun using newer tools to encourage enrollees to use lower-cost drugs in pharmacies. For example, most Part D plan formularies now use two generic tiers, with lower or zero copays for preferred generics. Most plans now offer preferred cost sharing if an enrollee fills their prescription within a specific pharmacy network.

As we have discussed in previous meetings, sometimes the use of these tools has been controversial,

involving tradeoffs between beneficiary access and cost control; however, some plans are trying to use these tools as ways to deliver Part D benefits more efficiently. Given how plan management tools are changing, you may want to discuss whether you want to broaden the wording of the Commission's 2012 recommendation to encompass these newer approaches.

Some of you asked that we look at providing greater financial protection to enrollees who reach Part D's out-of-pocket limit. LIS enrollees do not pay cost sharing above the out-of-pocket limit, but enrollees without the low-income subsidy still have to pay 5 percent coinsurance on each prescription above the limit. So, in addition to paying in 2015 about $4,700 in cost sharing, those enrollees continue to pay 5 percent, sometimes for very expensive drugs.

In Medicare Advantage, enrollees have a hard cap on the cost sharing they pay for their Part A and Part B benefits. So we looked at a hard cap in Part D too. One thing to note, though, is that even though it is burdensome, cost sharing may be providing some drag on manufacturers' decisions about how high to set a launch

price. One way to limit that burden is to keep some cost sharing, but charge fixed-dollar copayments that are more predictable than percentage coinsurance.

We estimated that if we just look at one year, 2013, Medicare program costs for having more complete coverage above the out-of-pocket limit would be relatively small, a few hundred million dollars. The reason that it's small is that today, most enrollees who reach the out-of-pocket limit receive the low-income subsidy, so Medicare is already paying the 5 percent cost sharing for them.

There would be new program costs for extending coverage to a smaller number of non-low-income subsidy enrollees. Medicare would pay for about three-fourths of the new benefits, but the rest would be paid by all Part D enrollees through slightly higher premiums.

There are some cautions we need to keep in mind, though. First, this is just a one-year snapshot of costs, but those costs would continue over many years; and second, there are a couple of factors that could push up costs quickly. The numbers of non-LIS enrollees who reach the catastrophic part of the benefit is growing faster than for LIS enrollees, and there are a lot of specialty drugs in

the development pipeline, which we expect to be launched at higher prices.

So, to summarize, here are the general areas of policy options you may want to discuss: reducing or eliminating Medicare's individual reinsurance, broadening plans' flexibility to use formulary tools, perhaps revisiting the Commission's 2012 recommendation regarding low-income subsidy cost-sharing, and fixed-dollar copayments above the out-of-pocket limit.

With that, we'll open things up for your discussion. We would appreciate hearing your comments about this material as well as your guidance around policy options with the intention of potentially developing the ideas into recommendations this spring, and we anticipate pulling this all together for a chapter in the Commission's June 2015 report.

DR. CROSSON: Thank you, Rachel and Shinobu. Not only comprehensive, but clear and actionable as well. So we appreciate the work.

Can I see hands for clarifying questions? Kate.

DR. BAICKER: Thanks. This is a lot of really helpful material.

I had a question on slide 6. I'm still slightly unclear on the relationship between the two components of the bids that the plans make. You make the point in the chapter, which is a really persuasive one, that if this is just about uncertainty it shouldn't be systematically positive on one and systematically negative on the other; there is something else going on.

Can you help me understand the connection between the two parts of the bid, if any, and what the implications would be of combining that into one to sort of make the negative and the positive more -- less separable, if that makes any sense?

DR. SCHMIDT: Okay. So I'm not sure I can adequately do the second part, but --

DR. MILLER: As far as we know.

DR. SCHMIDT: So when plans are submitting their bids, they not only bid on what the basic benefits are; they have to anticipate how much reinsurance they will get as well because that is going to be the basis for the prospective payments that they get monthly for reinsurance, too. So they're bidding on both of those pieces at the same time.

Do you want me to go through what we discussed last time in terms of the bidding incentive, or was that your question?

DR. BAICKER: So I'm still troubled by the bidding incentive, but I'm not entirely sure that I understand what the implication is of letting them bid separately on those components versus having -- and maybe this goes more towards the -- this is a different flavor of limiting the reinsurance subsidy.

But I wonder; is there the -- how much gaming is -- how much potential for gaming is introduced by this bidding structure?

MS. SUZUKI: So one thing we talked about last spring is that the bid that combines the expected reinsurance and the portion for the basic benefit sets your premium and your direct subsidy payments.

What we've seen is that the reinsurance portion has been lower than the actual. But at the end of the year, when CMS reconciles the actual with the bid, they get the full amount back.

And so we've seen the underestimate on that portion, but it seems like, on average, plans were

overestimating the benefit portion, which, at the end of the year they also do a reconciliation to figure out how much of the difference would be subject to the risk corridor payments. For that piece plans have been paying back to CMS on the average, which means that they were overestimating how much of the cost would be in that part of the benefit and they kept some of that amount as extra profits.

DR. BAICKER: And is the reconciliation on those two parts symmetric, or is one full and the other partial?

DR. SCHMIDT: I'm not sure. I mean, you get the full amount of reinsurance back if you underbid on that and it's ultimately higher. But because of the structure of the corridors, there's range where you get to keep extra profits. Right?

DR. MILLER: So kind of think of the corridors as symmetric, if I'm following your question, but remember you get to keep -- right.

DR. HOADLEY: So, in that sense, the reinsurance, you're getting all the money that you could have gotten back; in the risk corridors, you're only getting the money relative to the size and the rules around the corridor.

DR. SCHMIDT: And this is through 2013. We don't yet know what's going on with 2014.

DR. HOADLEY: I just think it's worth emphasizing: On slide 6, the reinsurance payments that are rising, those are reconciliation payments. On slide 5, you're showing the overall rise in reinsurance. That's the total pot of reinsurance.

So you could have had a situation where the line on 5 was going up, but the reconciliation on 6 was constant or going down. Those operate kind of independently of each other.

DR. SCHMIDT: That's correct.

MS. BUTO: This is a follow-up also. I just wanted to -- getting back to the points that Jack and Kate are making, is the beneficiary -- since the premium is a combination of the two, is the beneficiary a portion of the premium where what the beneficiary has to pay lower than it otherwise would be, or higher?

So, in combination, it's lower even though on the basic benefit, if that were the only thing the premium were based, they'd be charged too much. But because of the reinsurance, it ends up being lower.

DR. SCHMIDT: That's correct. In the mailing materials, we have a table in there that kind of gets to that point.

DR. NERENZ: On slide 14, the last bullet point, does the phrase "newer tools" there refer to just back up to the immediately prior bullet point, or is there a set of other newer tools that we're talking about here?

DR. SCHMIDT: That's a good question.

DR. NERENZ: Thank you.

DR. SCHMIDT: There's always going to be evolution of tools. I mean, we're kind of scanning the market, and we'll come back to you in January telling you about more recent things, but there's, for example, use of specialty pharmacies to deliver those types of medicines.

So it could evolve further, and so this is a bit open-ended wording for that reason, but I think we specifically had in mind those two things in the PowerPoint.

DR. NERENZ: I just wanted to clarify what you were asking us to think about.

DR. COOMBS: We may have covered this in the spring. Did having the managers make a difference in their

ability to predict both the cost and the out-of-pocket expense -- did having the manager impact that at all in terms of the plans --

DR. MILLER: What do you mean "the manager"?

DR. CROSSON: The pharmacy management.

DR. COOMBS: Yes, the PBMs. Having a PBM, did that make a difference with overall ability to correlated out-of-pocket projections or total premiums?

DR. SCHMIDT: All of the plans are using a PBM.

DR. COOMBS: Right.

DR. SCHMIDT: I mean sometimes a contracted one, sometimes internal to their organization. So I'm not sure what the counterfactual would be.

DR. COOMBS: So there was no factor, in terms of them lending themselves to information, that may have changed their ability for out-of-pocket expense. You know, cost. Were there any kind of predictors with utilization of those managers in any way?

DR. MILLER: If I understand the question, the answer is no, we didn't see a pattern where if you had this particular structure in your plan you were different in how you bid. I'm also not sure how much we actually tried to

pore through it and answer that and look at that, but in answer to your question, no, we're not aware of that.

DR. COOMBS: I was just wondering if there was a subset that had the plan had a better capacity to predict, and if it were so what did they have, and what is some of the intrinsic feature. And I'm not sure that we covered that.

DR. SCHMIDT: Well, in the chapter from last June, we actually show some reconciliation data by plan sponsor, by parent organization. And over the time frame, pretty consistently, at least for the largest ones, we were all seeing the same patterns of behavior across all. I don't know if that gets to your question or not.

DR. NAYLOR: So, on slide 13, I'm wondering if you could comment on how much flexibility in formulary tools, how important protected classes is, in thinking about possible changes.

I mean, what kind of benefit might be derived from that? Do we have any experience from commercial benefits that don't have protected classes and so on? So how much might a policy shift in this?

And I know CMS did not act on the recommendation

around the two classes. But how much of a lever might this be, and the recommendations around flexibility?

MS. SUZUKI: So I'm not sure that we have something that's quantifiable, but our sense is that when plans negotiate with drug manufacturers for rebates, having these protected classes does not give them the leverage they have in other classes to obtain rebates from drug manufacturers. They know that you have to put it in your formulary, and that's the strongest tool they have to negotiate discounts and rebates from them. Our sense is that by removing the protected status it would allow them to negotiate better.

DR. SCHMIDT: And what CMS has proposed to do is have kind of a process for evaluating what should be a protected class or not based on trying to think through whether the potential for harm to beneficiaries is severe, hospitalization or severe injury if they don't get relatively quick access to it, or if it's a sort of condition where you need access to multiple types of medicines to figure out which one is appropriate.

DR. HOADLEY: Also on 13, I wonder what we know about on the mid-year formulary changes. You mentioned

that if a drug is in a class that isn't already sort of full in the sense of the two drugs, or the one drug, in the subclass. A lot of the cases for new drugs are drugs that will eventually be in their own subclass, at least, if not class.

But I don't think CMS normally -- I mean, the process of going through the USP is much slower than sort of the mid-year. I don't know how, in practice, CMS sort of applies that rule as well as how -- it seems to me I've seen some new drugs do have prior authorization requirements. So, again, I don't know how much we know about sort of what CMS's practice is and how that kind of thing is enforced.

MS. SUZUKI: So I would say we're still learning about this works in practice, but in general, plans cannot make any changes to their formulary the first two months of the year. It seems like for negative formulary changes the rules are a little bit more strict than enhancements where they're adding drugs.

At least reading the rules, it seemed like CMS may have up to 30 days to approve or deny a request. Once it is approved, they still have to give 60 days notice to

the beneficiaries and prescribers about the change in the formulary status.

And I believe the deadline for submitting changes is July, and that limits how often you could apply new negative changes.

DR. SCHMIDT: Yeah. And in speaking with plans about some newer drugs that come out on the market mid-year, you can get approval from CMS to use prior auth. We're learning about the difficulty, or how arduous that process may or may not be. But it is possible to put prior auth on it, but it has to be limited to what's on the FDA label. So for some plans, for their commercial business, they might put more restrictive requirements on.

DR. MILLER: I also think some of what we heard when we were talking to plans is there's a certain -- there may be some variability across the country on how, you know, much response you can get when you're trying to make a change. And, obviously, the plans were very concerned when Sovaldi came on, and were trying to get changes, and were feeling like they were struggling.

DR. CROSSON: Kathy.

MS. BUTO: Just a follow-up on the same slide.

So it sounds like the restrictions on using utilization management tools for protected classes is mostly in regulations as opposed to the law. Or, does the law restrict the use of utilization management?

It sounds like there is some discretion there and it just isn't being allowed for the moment in regulations. Is that right?

MS. SUZUKI: I think that's correct. They have -- CMS has put out a regulation saying that exception has to be based on scientific evidence and medical standard, and it also requires public notice and comment period for approval of --

MS. BUTO: For any use of utilization management in this group.

MS. SUZUKI: For protected class drugs.

DR. MILLER: I mean, maybe a broader point and a broader way to think about it is as you decide on your direction, and then we come back and construct regulation, or I mean recommendations, some of these might be changes in law, so maybe asking the Secretary to look at things.

And on some of the management tools, I mean, a way you can think about it -- I'm not saying you have to,

but a way to think about it -- is you could make different rules for very high-priced drugs. And what that cut point is, of course, is a question.

And I think what we're talking about is when something happens mid-year and some very expensive drug shows up, should there be some set of rules that lets the plans kind of get on top of it and not have to go through such an arduous, I think was the word, process?

DR. SAMITT: So this may or may not be a round one question, but on slide 12, I guess I'm having trouble reconciling when we think about reducing or eliminating reinsurance, on top of your comments about the fact that this may create exposure, especially for biologics and other specialty drugs. How do we reconcile that?

Do we know to what degree the payments for reinsurance specifically apply to these classes of drugs?

Are we thinking of holding plans accountable for things that they can't be accountable for because of prices related to biologics, et cetera?

DR. SCHMIDT: That's a tough question. In some sense, yes, but that was kind of also the reasoning behind allowing a little more flexibility in the formulary so that

you can --

DR. SAMITT: I got it. So they go hand in hand.

DR. SCHMIDT: Right.

DR. MILLER: And you're right; it's a round two question.

But in all seriousness, I mean, there is a tension here. I mean, Medicare has constructed a situation here where the plan acts as the intermediary in negotiating and formulary coverage and all of that. And to the extent we just say, well, the plans can't control it, then all those costs just roll into the program.

Here, we're trying to strike a balance between the plans' pressures that they're under and the tools that we're giving them at the same time. That's kind of the discussion.

And it will be very embedded, if not explicit, in round two.

DR. CROSSON: More to come. Rita.

DR. REDBERG: This is a round one question.

DR. CROSSON: Good, good.

DR. REDBERG: I say. On page 14 of the mailing materials, I was trying to understand more about the

rebates. First of all, how do we get the rebate information, and then where does that get figured in when we're calculating reinsurance and risk corridors and that sort of thing?

DR. SCHMIDT: Right. So CMS calls this direct and indirect remuneration. And so they have to report. The plans and their PBMs are reporting this information to CMS, how much they've gotten from the manufacturers as rebates.

And there are rules that CMS puts out, or guidance, on how to allocate that rebate across Part D spending, and basically the answer is smoothly. So even though some drugs that may be used more heavily by people who reach the out-of-pocket limit may not be obtaining rebates because they don't have as much competition going on. All of that rebate that comes back is just spread out proportionally to total drug spending.

That's essentially how it works.

DR. MILLER: And just to be clear on the "we," CMS gets the rebate data. Just for the public, we don't have access to that.

DR. REDBERG: Thank you.

My other round one question was also on the mailing materials. On page 17 there is a table that is very helpful to try to understand the difference in drug utilization between LIS enrollees and non-LIS enrollees.

I'm wondering if you also could tell us what are the top drug categories or any specific drugs that were more common in the LIS enrollees?

MS. SUZUKI: In the past, this is not the most recent data, I think when we discussed a long-term copay policy recommendation, we saw some of the very common classes like diabetic therapy or antihyperlipidemics, antihypertensives, those came up a lot.

There may have been some shift, but I would imagine those are going to be pretty dominant for LIS population.

DR. REDBERG: More brand name than generics, you've said before.

MS. SUZUKI: Yes.

DR. MILLER: And I think that was the surprising thing, I think, when Shinobu did this work a couple of years back, is I walked around with the perception that the LIS folks used expensive different drugs. And they do, to

some extent. But you find a lot of the common drugs, just more name brand, like you said.

DR. CROSSON: I think we're ready for round two.

So in thinking about how this is going to go, I think there is a couple of, sort of, procedural issues you have to deal with here. We have roughly about 10 options on the table at the same time; three options with respect to reinsurance -- don't change it, change it some, change it a lot. And then, with respect to plan flexibility, at least three options, perhaps more. The issue of LIS copayments, trying to introduce incentives there, probably two options. And cost-sharing above the out-of-pocket limit, at least two options there, as well.

So my thought was that if we tried to kind of do this in the option, without any structure, we would be all over the place, the time would run out and we would have no conclusions. On the other hand, if we took them one at a time, we'd be still here at five o'clock.

So at some risk, what I thought we would try to do is this: because there's another perspective here. And that is, as has been pointed out during Craig's question a few minutes ago, among these options there are trade-offs.

If you take one option, it makes it harder for the plan for example, it makes it harder for the LIS beneficiary for example. Whereas other options would be the reverse.

So this sort of situation arguably can lend itself to a package. In other words, we try to construct a package that includes one or more options in all of these categories and then eventually perhaps even bring it forward as a package.

So what I thought we would do, if you could throw up the just made slide, is to start out with a straw man package and suggest that we have a discussion predicated on this. Do you like the package? Do you not like the package? Are there elements of the package that you feel strongly need to be changed? If so, how would that influence you on other elements of the package?

Let's see where we end up in about an hour on that basis. Okay?

So the proposal here is that we reduce the Medicare reinsurance from 80 percent to 20 percent. That's as opposed to doing nothing and as opposed to eliminating it entirely. Why would we not eliminate it entirely? I think Rachel mentioned, in fact, that there is some

question about whether or not by eliminating it entirely we would eliminate disincentives to cherry-picking among the plans. At least, that's one issue.

That we would, in exchange, provide greater flexibility to the plans in terms of their ability to use some of the tools that exist, for example, in the commercial world. That would include reiterating our former recommendation to remove the two drug classes. We had anti-immunosuppressants and --

DR. SCHMIDT: Antidepressants.

DR. CROSSON: -- antidepressants from the drug classes.

And for high cost drugs, ease the -- at least the procedural processes around getting approval for mid-year formulary changes which appear to be in place. It seems like, Kathy, that could be done by CMS.

And in addition, allow plans more flexibility in using smaller -- and intervening to have smaller supplies for certain drugs provided, even if it's at a more frequent basis.

We would then update our 2012 LIS copay recommendation in two ways: consider the introduction of an

additional tier, a non-preferred generic tier for example, or other tier structures. Or in other ways broadening the difference between the copayment for generic drugs and for brand name drugs, which could include, for example, having zero copayment for generic drugs and a larger amount of copayment for brand drugs that currently exists.

This doesn't necessarily involve providing only choices for more out-of-pocket payment for beneficiaries. It could include less or zero, but it does broaden the difference between generic and brand name, and there are several ways that that could be done.

And in addition, allowing for the plans to use preferred pharmacy networks with potentially different copayments for beneficiaries who choose to use preferred pharmacies versus non-preferred pharmacies.

And then the last piece has to do with beneficiary cost-sharing above the out-of-pocket limit. Here there would be two proposals. One would be for the non-LIS beneficiaries over the out-of-pocket limit, and that would be to apply a modest, as yet to be determined, fixed dollar copayment to limit the exposure for those individuals and for the LIS beneficiaries to provide for a

nominal copayment but only for brand name drugs for those individuals over the out-of-pocket limit.

So in almost every case, or in the combination of these elements, there's a little give and there's a little take back. So that's the straw man, there are arbitrary choices made here, obviously. But it's put forward, I think, as a discussion piece but one that we think is reasonably balanced.

So let's -- Mark, do you want to comment on that?

DR. MILLER: You're good.

DR. CROSSON: Let's start on that basis. Jack, you have the floor.

DR. HOADLEY: So I think this is helpful to try to start framing this conversation, and I'm going to go through my take on most of these.

I would actually add sort of the one that is missing, but sort of intentionally, which is the risk corridor where the presentation suggested the potential to not make any change and I think you're essentially endorsing that by not listing it. But I think that's worth being explicit about. I think that's a good decision. That is a tool that allows plans some flexibility, as we've

seen in the 2014 numbers. I think those are very telling that, on the one hand, in the past it protected the government in terms of high profits. In 2014 it seems to have protected the plans against the unexpected costs of a new drug and that may well be true in 2015, as well.

We could, at some point in the future, think about some restructuring where there was something more across the board for, you know, a new drug appeared on the scene in mid-year and it added costs. And rather than it being plan-specific, maybe you just add an increment. That's something we can think about a couple of years down the road.

On the reinsurance, I'm with you on that. I think something like a 20 percent change -- and I think, you know, one of the things that I'm struck by is, first of all, that balances some of the different effects, as you've said.

Potentially, it should not affect beneficiary premiums. We've talked about -- in the presentation -- talked about sort of things that might push them in either direction. So maybe that's a sense that on average it shouldn't have an effect. It may turn out to have an

effect because anyone of these things -- and that's why some of these other items are on the list.

You know, the point was raised about the single source drugs and the lack of leverage. In a sense, that's already true. I mean plans, although they are protected by reinsurance, that's not a full protection for them. And so, they're dealing with that today. This basically says to plans that have taken a Hep C and said in order not to be completely swamped by the cost we're going to put in fairly strict prior authorization. There's some negatives to that, from a public health perspective, from a beneficiary perspective.

And so I think through all of this we should pay attention to how do we monitor the use of prior authorizations? How do we monitor the use of exceptions to make sure that beneficiary access is protected for drugs that are important? I think that's the part of that tension that we haven't talked about quite as much as we should on these kinds of things. It's going to come up on some of the other issues, as well.

But I do think moving that reinsurance threshold is a sensible approach.

On the plan tools, I have sort of more questions and I'm not sure I'm there on some of these -- as you put it -- straw man recommendations.

I think with the protected class changes, we really do need to be very careful about what the implications are for beneficiary access. And I think -- I do have some sense that CMS was pretty thoughtful when they thought about their proposal for class, like the antidepressants, where it's mostly generics.

I think part of the issue is I don't take it full value, some of the critiques from the plans who say our hands are tied. In many cases, plans are listing far more than the minimum drugs in their formularies in this two drugs per class -- now I'm not to my protected here.

It's typical for plans to be well above those thresholds in many classes. There may be individual cases where they feel constrained. In a class like antidepressants where most of the products are now generics, they are likely to continue to offer all of those generics. It may give them the ability to say to some new "me too" brand name drug that comes on the market, we can try to limit use of that. They already have the tool of

putting it at least on a non-preferred tier.

So I'm not sure that there's a lot harm necessarily being done if classes are thought of. If two years from now there's new therapies in the antidepressant class or new evidence about substituting and switching people on drugs, that's part of the logic of these protected classes, is that there are things where we think there's some evidence that patient shouldn't be switched around from product to product so readily as might be the case on a proton pump inhibitor or something like that.

So you know, I'm potentially okay with some changes there, but I think we want to think through what the beneficiary access applications are as well as how big a help that is to the plans. I mean, if it's not that big a help, then is it worth risking some harm to the beneficiaries?

The new drugs, again I'm not sure -- I'd like to understand, as per my previous question, how much limitation. It seems like in the Hep C case plans were able to have fairly strict prior authorization requirements. I don't know how much of that had to do with the timing of things that they could do at the beginning of

a new plan year versus what they could do in mid-year, and sort of how much of the use fell mid-year onward and the sort of arbitrariness of the calendar. If a new drug gets introduced -- and again, there's a lag time for plans to put a drug on formulary in January.

Right now, if you go on the plan finder and look for the PCSK9 drugs which are approved on the market, they don't show up anywhere. They're not even in the plan finder lookup function, as of a few days ago when I tried to look them up.

So I think there's definitely a reason for more understanding. I do think, my sense is it's not really a negative formulary change to say we're adding a new product, like a PCSK9, to the formulary with a utilization requirement because that's adding access to the drug that wasn't there before, although with restrictions.

So there may be a logic to saying if you're going to add a new drug, being able to add restrictions at the same time is certainly quite reasonable.

DR. CROSSON: But Jack, I would just insert for a second. My understanding is it's not correct that CMS has been interpreting that as a negative change.

DR. HOADLEY: Right.

DR. CROSSON: So as this has been implemented in the field, it has that effect.

DR. HOADLEY: I get that point. That's why I'm saying I think, in effect, I'm not sure I see it as a negative change. So therefore, to say that's what the rule should be within that mid-year change -- you're adding a drug but adding it with a restriction -- might be not viewed as a negative change....to be double negative.

DR. MILLER: I took your point. We now have access to the drug. By the way, there's a management overlay.

DR. HOADLEY: There is limited access for the moment and we could broaden the access next year or we could further narrow the access next year in the new plan year.

On the LIS tools, I've always -- I wasn't on the Commission when this was done. I think I have, again, mixed feelings about some of the ways this is done.

I do believe that the option of creating a zero copay for generics as an incentive is very useful. I've done some research on the impact of a zero copay. I think

we have to be careful that we're not unnecessarily adding copays.

So one of the things I think was emphasized when the recommendation was made a few years ago, that this might not apply to a class where only brand products were available. So I think we need to continue to remember, if we're going to move in this direction, some of that. What does that mean now, in terms of multiple tiers of generics?

I want to think through more what that would mean. I think we would need to work through some examples. Are we saying they could do a zero dollar, $2 kind of differential for two generic tiers? I think that's just something where we need to understand what that might look like better, and I think we need to be careful that we're not making it tougher for these low-income beneficiaries.

The same thing with the preferred pharmacy networks. There are concerns about the access to these networks. I think one of the things we need to think about is that LIS beneficiaries, in many cases, may use different pharmacies based on geographic location or even just pharmacies that have been more welcoming to certain kinds of patients. And since, in general, it tends to be the

chains that are in the preferred pharmacy networks, it may not be the chains that are most often serving some of the lower income areas.

So I think we really need to be very careful and look at what the access dimensions are before we do something that allows differential copays to apply.

And then last, on the out of pocket limit, this is one obviously I've raised several times before. I just wanted to throw one data point in that we've been looking at for some analysis that hopefully we'll get out and published in a few weeks.

But we've been looking at some of the high cost specialty drugs, the cancer drugs like Gleevec, the Hep C drugs, the rheumatoid arthritis drugs and the MS drugs. And when somebody takes one of these drugs and just to simplify them, say that's the only drug they're taking, not even loading them on top of their regular course of therapy.

The amount that the beneficiary taking, say Sovaldi, pays out of pocket total across the year, is something like $3,800 in the catastrophic phase, and another $2,800 that occurred under the cap. So they are

actually paying more than half of their out-of-pocket cost in the phase that we think of as they're being protected as catastrophic coverage.

So people quite often jump into thinking there's an out-of-pocket limit on Part D. For these kinds of situations, it's so much not an out-of-pocket limit that they're paying more above the catastrophic limit out-of-pocket than they are paying out-of-pocket below.

That's true for Sovaldi. That's true for Gleevec. That's true for Copaxone and several other examples that we've looked at.

And of course, it's equally true for somebody who's taking a dozen brand name drugs or a mix of 15 drugs of brands and generics that adds up to similar costs.

So you know, this is why I sort of made this point before, that we really need to provide some protection and catastrophic coverage that's really catastrophic. Personally, I would rather see it be a hard out-of-pocket limit. That's what we've done on the exchange world. That's what we've even talked about for Medicare more generally. That's what we require Medicare Advantage plans to do, although not on the drug side of the

benefit.

So if it works in those sectors, it seems like a hard out-of-pocket cap to me. And I'm skeptical generally on the argument that it provides much of a drag on launch prices. I think launch prices are driven by a whole lot of other things that are not this. And I don't know whether a small fixed copay really changes that equation over a zero.

My preference still would be to do a hard cap on the out-of-pocket thing. But I certainly would prefer a nominal copay over the status quo.

So I'll stop with that.

DR. CROSSON: Okay. So let me see the hands again, like the package, don't like the package, would like to change this element of the package? And if you want to change an element, comment a little bit on what other element you might change so that we come out with a balanced package at the end. That's my --

So I see Craig. Let's march this way.

DR. SAMITT: So I like the package. The one part of the package that I have a question about is the first, and it goes back to the questions, the inappropriate Round 1 question I asked about are we exposing the plans to too

much risk, especially because of biologics and other specialty drugs, and could we envision, for example, an alternative to the first recommendation being elimination of the reinsurance for everything but classes of drugs, so specialty or biologics. And there is higher levels of reinsurance for that class where we feel the plans may not have significant influence but complete accountability and risk for pretty much everything else. I don't know how that all settles out in terms of rounding out the proposal, but that would be my only modification.

The others -- and I would say the combination of all of them is what's critical -- all made complete sense with Jack's additional perspective and caveats.

DR. CROSSON: Okay. Thank you.

Kathy?

MS. BUTO: Yeah. I don't have a problem with the first one, particularly if we keep the risk corridors. I guess that was the caveat that Jack laid out.

I do actually think -- I haven't thought this through, but Craig's suggestion about having categories that would be subject to reinsurance and others that would not might really disadvantage beneficiaries, particularly

if they are taking a lot of different drugs and only the copays that go for the specialty drugs would be counted. I don't know. But it just seems to me that it might have some unintended consequences.

I like Jack's recommendation to move to an overall cap as opposed to having the two copays, and the example was interesting. I'd be interested in seeing what comes out.

And I think we meant to be more explicit about the fact that under plan flexibility for high-priced drugs, we're also talking about not just midyear formulary changes, but a greater flexibility in the use of plan tools, whether it's midyear formulary or otherwise. I got the sense that within the six protected classes that there are real constraints on the use of tools, regardless of whether they're midyear formulary changes or not; that, generally, their hands are tied.

I personally would rather see a greater availability of things like antidepressants and cancer drugs and so on but some flexibility to use tools than to limit the numbers of drugs. Just recognizing that they're used in combination and individual circumstances dictate

which drugs are best and so on, and I think there is an issue with some drugs. It's good to stay on them and not have them change from year to year kind of thing.

So, anyway, I think we meant to be explicit about more tools, but I would put that in there, and that's just where I stand.

DR. CROSSON: All right.

DR. MILLER: Can I just put one marker down? I don't know whether this is Cori. This variable cap by drug in addition to the concerns Kathy raised, I also wonder about other incentives in kind of an insurance design kind of way. And since you weren't doing anything, I thought maybe --

[Laughter.]

DR. MILLER: -- I'd ask you to start thinking about that because I see what he's saying, but I start to think of like a whole bunch of gaming issues.

DR. CROSSON: Okay. Rita, do you want to come in? Rita, yeah. Okay.

DR. REDBERG: Just to comment.

DR. MILLER: Yeah, yeah, yeah.

DR. REDBERG: So, in general, I like the policy

options. I am concerned. I think the idea of reducing reinsurance is good, and I actually was wondering if the risk corridors was time to go. But because looking at sort of the bigger picture, I worry that these are all being used to prop up a dysfunctional system. There are a lot of indications that our drug plans are not serving Medicare beneficiaries in the best way, in that I mean we don't have any measures, for example, looking -- you said we want to assure access to appropriate medications, and I think that's true, but there's nothing in here that assures any of this is appropriate. And there's a lot of evidence that a lot of these are inappropriate medications.

So, without any kind of -- I think we need sort of measures looking at appropriate use and overuse of medications. In that article that came out in JAMA a for example days ago, showed this incredible increase in prescription drug use in the U.S. in general, with 60 percent of people taking at least one drug, but if you look at the table where it breaks it down by age, polypharmacy and people over 65, meaning five drugs or more, was at almost 40 percent. I'm just not sure that everyone needs to be on all these drugs that we're on, and then there are

all of the other problems of them being very expensive.

And the other point that I don't think we currently look at in approval or in coverage is that it's not clear to me that we even are looking at data that was gathered in people over 65. So risks and benefits are going to be very different in the elderly than they are in younger people, and most of these drugs were studied in younger people. And so I think we need to be sort of in the bigger picture. I hate to prop up a system that's just not working well for our beneficiaries, and there are a lot of indicators that our current drug system is not working well. It's getting more and more expensive. People are on more and more drugs, and they're not getting healthier as a result. So I think we want to take hold of that and try to improve the outcomes and what we're actually paying for because that's a lot of money.

The last comment, 7.6 percent of enrollees account for 47 percent of Part D spending. I mean, that's astounding, and I think we need to look kind of closely at what we're getting and what's going on there.

DR. CROSSON: So just to be clear again -- and I didn't reiterate this in the beginning, but we did at the

prior meeting discuss the fact that we intend to take a comprehensive look at drug costs. In the meantime, we are continuing and trying to finalize the work that has been begun already.

So some of the things we're doing, like with this work on Part D reinsurance, it seems like a rifle shot, when in fact I think you were suggesting a militia all armed with shotguns, and I'm not sure whether that's the right analogy here, probably. I know Mark gets a little concerned about my use of metaphors on occasion, particularly military or sports, so I'll --

DR. MILLER: This is true.

DR. CROSSON: Right, right.

[Laughter.]

DR. CROSSON: But the larger set of issues you bring up are still on the table for the foreseeable future; however, here, we're trying to advance and complete the work that we've begun already on this particular issue or set of issues.

Bill?

MR. GRADISON: I think this is a reasonable set of proposals. I think I'd find it easier to support it in

a year than I do right now because I think there's some very dramatic changes, which we've discussed, that are taking place in terms of new drug introductions and some of the discussion about pricing.

I'm concerned that we may not be able at this point to fully understand, understand as fully as I would like to understand, how these changes that are taking place in the marketplace might be impacted by the list that's up there. Sometimes maybe slowing down, getting another year of data isn't necessarily a bad thing. I'm not recommending inaction. I'm just a little uneasy about acting at this time.

DR. CROSSON: Thanks, Bill.

But I guess two predicates there, number one, at least the postulate so far is that maintaining and not changing the risk corridors provides a level of protection against unexpected cost from introduction of new expensive drugs, as you say. And I guess the second point I might make is that the time frame for us to complete this deliberation and issue a report takes us to June, and my guess is, during that time, not only will we have time to consider things, but we'll have more time to understand

what's going on in the environment.

David.

DR. NERENZ: I generally like the package, so we've talked about a few tweaks, and I haven't yet heard something that's directly one thing conflicting with the other. So it's easy to say I sort of like it all so far.

Particularly, though, the structural balance, I think if we're going to add an element, say in the first bullet that puts the plans at greater risk, then I think absolutely there has to be some corresponding additional flexibility or tools, which led to my easier question of "What are those tools exactly, and are there some that we haven't yet thought of?" So all of that is just stating I think we're on the right track.

The only other thing I'd like to bring up -- and I am looking at page 25 of the materials we had -- this is about the diagnostic-based risk adjustment system. I hadn't heard a lot about that. In fact, I had to thumb through here just now to make sure I remembered there even was such a thing, but it appears to be in there. I would think that that may have a part in this package somewhere because, if the driver of individual high cost is something

like a new Hep C diagnosis or a new cancer diagnosis, it would seem like some of the risk could then be ameliorated by an adjustment system that would affect what -- the CMS subsidy? Is that what that risk adjustment drives?

So it could be part of the package that if we're going to add some element of risk, some of what the plans cannot control, like a new cancer diagnosis, could perhaps be picked up perhaps better -- but we don't know the details -- through something like the RxHCC systems. I just want to make sure that's in the picture as well.

DR. CROSSON: Go ahead, Rachel.

DR. SCHMIDT: So, yes, the capitated monthly payments that Medicare makes to the plans are risk adjusted by that system that you're referring to.

DR. NERENZ: And are they adjusted monthly? If a member of a Part D plan develops a new cancer in a year, when does that get picked up or adjusted for?

MS. SUZUKI: The diagnoses, I believe there's a two-year lag.

DR. SCHMIDT: And in the case of Hep C, for example, OACT, I believe, did a manual adjustment for beneficiaries that started to use those drugs, to reflect

the higher cost of that particular specialty drug, because it was so expensive. So they went in and tweaked those particular condition categories.

But, in general, the RxHCC, if you did the first approach, the first bullet of reducing reinsurance, that means the capitated payments would make up a bigger proportion of Medicare subsidy. Yes, the risk adjustors are very important for making sure it doesn't lead to more cherry-picking. CMS would have to recalibrate the risk adjustors to reflect the higher level of capitated payments, and yes, we probably should think about whether or not there's more situations where manual adjustments or a different kind of approach might work better.

DR. NERENZ: Again, I don't have the specifics. We haven't talked about it much in depth. I'd like to see us pay a little more attention to that because this strikes me as kind of a strange form of insurance in general. It's only one bit of the treatment of portfolio, and if we ask plans to be responsible for drug cost, it would seem like we'd want to pull away making them responsible for the diagnoses that people have or the new diseases they get because they have no control over that whatsoever. And

this mechanism seems to be a way of doing it, but if there's a two-year lag, it seems to be not -- then we get into some questions of what's the stability of plan membership.

If some of your members developed cancers this year, are they still with you as members two years from now when the HCC system picks that up? I'm guessing many of them are now. So a quicker pickup would just be one precise thing that maybe could happen.

DR. SCHMIDT: I think the two-year lag issue was with respect to recalibrating the risk adjustors, not necessarily whether an individual beneficiary has a specific condition or not.

DR. NERENZ: Or whether a payment to a particular plan was driven by that. That's the leg I'd be interested in, is how long does it take for that new cancer diagnosis to be picked up in the payments that are made through that mechanism to that plan.

DR. SAMITT: And I guess I would also add that this discussion sort of helps mitigate some of my concerns about the first category, that if the risk adjustment were more real time, to reflect differential diagnoses for a

particular plan, if there were such a significant lag and that was accounted for in the benefit, the premium essentially, then -- or in the capitation -- excuse me -- then I'd be less concerned about changing the reinsurance levels or the need to create distinct reinsurance for certain classes.

DR. CROSSON: Mark had a point?

DR. MILLER: No, no. I'm all right.

DR. CROSSON: On this, Kathy?

MS. BUTO: Yes, on this, just a related point. And I am not recommending this, but I know that in Medicare Advantage, if something comes online, a new procedure, midyear, there is some ability to adjust and pay the plans. I don't think the whole amount more but maybe some portion more, and that's probably what the actuaries did manually. But I don't think we want to lose sight of that. There is some flexibility to make some payment adjustment.

DR. CROSSON: David again? No.

That is a very good point. I mean, I think to the extent that we reduce or increase the risk to plans, then the risk adjustment process is going to come into sharper focus, and the question of whether it's adequate or

not is a realistic question to ask. And I think the question of whether it could be strengthened in some way again also.

Coming around this way. Cori.

MS. UCCELLO: So, just to clarify this risk adjustment discussion, there are two aspects of this. One is calibrating the model so that the spending in the model reflects the new spending of the drug that's coming along. So that's one part, and that's where some of this lag is coming in or where there is an ad hoc adjustment.

Then there is the second aspect of whether the risk adjustors, whether the diagnoses or whatever is used in that model, are done prospectively or concurrently. Is Part D risk adjustment prospective so that in the middle of the year, somebody gets a diagnosis that would have resulted in a higher payment and higher cost, that would be taken care of, where it would not be taken care of in a prospective system? And I think it's prospective. Yeah.

So it would be okay the next year, somebody who starts Hep C in June or November or something and carries over to the next year. That new spending would be reflected in the risk adjustment for the next year but not

the current year. Is that right? Okay.

DR. MILLER: And the tension that -- and I want to be really clear that I think the notion of -- and Jay and David's points about risk becomes really important. None of my comments are in any way disagreeing with that. But your tension you'll always have in thinking about this is how much you do it in real time and how much you pass through. So if you say, okay, there's a big expensive drug, so we'll give the plans a bump, then you're telling the manufacturers, "Raise your prices," okay? So there will be that tension.

And then whether you're measuring the risk of patient -- or sorry -- beneficiary based on what's done to them in real time, you're encouraging the plan to do more, and so there's always that tension and risk of how much perspective, how much concurrent.

All that said, I think your point is well taken, and to the extent that we mess around with the risk that they're under, we should be paying more attention to the risk structure.

MS. UCCELLO: Okay. So now to my regularly scheduled comments.

[Laughter.]

MS. UCCELLO: I am comfortable with reducing the reinsurance. I prefer that greatly to eliminating reinsurance altogether.

My concern with eliminating it altogether is that I don't think the risk adjustors can fully reflect the costs of these outliers, and even -- risk adjustment just in general is not great with outliers, so reducing it but not eliminating it makes sense.

My concern is that I don't want plans to have incentives to avoid certain people. I'm concerned about that, and I'm concerned with the plan flexibility changes not reinforcing those incentives to avoid certain people, making their formulary that certain people aren't going to want to join that plan.

So just striking the right balance when we're thinking about all this stuff is something that we need to do. So I'm not against any of this stuff, but just we need to keep that kind of thing in mind.

Building off of what Jack said, I really liked his idea of in the future, as we think about this, in terms of the risk corridors, maybe having some kind of ad hoc

adjustment when there are shocks and doing it that way as opposed to this risk corridor system.

But what I would do is perhaps combine that maybe with a one-sided risk corridor where the one-sided is only the plans have to pay back if they have gains that are higher than the target, so they would get kind of the other side enter, that ad-hockish kind of change, but keeping -- because we've seen, except for perhaps this year and next year -- we don't know what's going to happen in the longer term -- the history of this has been that plans have paid in, and you don't want to lose that recapture. So, as we think about this kind of in the future, just kind of maybe including that in the list of things.

I think that's it. I think the other stuff -- just again I just want to make sure that -- and I think we are trying to do this, but just trying to strike the right balance to making sure that plans don't have incentives to avoid certain people.

DR. CROSSON: Thanks, Cori.

Jack, you've made your points.

DR. HOADLEY: I want to come back at some point on --

DR. CROSSON: Well, go ahead.

DR. HOADLEY: So, this notion of sort of where does the reinsurance play in. I think one of the things that's important to keep in mind -- and it's based on the analysis that Shinobu did a few years ago -- is a lot of the people who are up in that reinsurance range, up in the catastrophic range, from the beneficiaries' perspective, are not necessarily the people who are taking these big, high-cost specialty drugs although there may be more of them, and that seems to be the trend. But there's a whole bunch of the people that are populating that category that are the polypharmacy people that Rita has talked about and the new study highlighted.

And that's where -- and so the reinsurance is dealing with the aggregate cost of the person, not sort of by class. So I think that's why we really want to try to turn some of that incentive, yes, to deal with the high-cost drug cases and make sure that when the PCSK9s hit the ground that they're not overused by a lot of people for whom they're not appropriate.

But we also want to have people dealing with the people that are taking 5, 10, 15 drugs and getting a higher

incentive to do the medication therapy management to address do the people really need to be taking these drugs, and that's where the plan kind of gets something of pass today. They have to do an MTM program. We don't think they're doing it all that well or enthusiastically, and they get a whole lot of their costs picked up. So if they let some of those people become high spenders, okay, that's just part of the cost of doing business.

What we're trying to do is make it more their cost of doing business and to give them more incentive to address some of those needs, and I think that's where these pieces can start to come together.

DR. CROSSON: Kate.

DR. BAICKER: So this is probably overly simplistic, but I think of the reinsurance piece as the important complement to the imperfection of the risk adjustment, as Dave was bringing up. You don't want plans to have a disincentive to enroll high-cost people. To the extent that the risk adjusters aren't perfect, the reinsurance helps pick that up.

So, if you're thinking narrowly about the cream-skimming incentive, you can be a little less concerned

about somebody who gets a new diagnosis in the middle of the year because they're already enrolled. So the cream-skimming component is about subsequent years, and that person's new diagnosis won't be new in the next year.

If you think about a different risk to the plans of suddenly there's a new drug for a group of patients that makes them much more expensive, that's financial risk. That doesn't play into the cream-skimming issue. That's about protecting them against broad, secular changes in cost that they can't protect themselves against because it affects a big group of patients.

If it's a narrow group of patients, I don't see such a strong need for federally backed reinsurance. They've got a lot of covered lives even if it's an incredibly expensive thing, if it's a small group of patients. They're insurers. They're supposed to be pooling risk, and so they should be able to handle that.

If it's a big group of patients, where suddenly this is a hard risk to offload because there aren't enough patients to balance it with, that's where the risk corridors come in.

And we're not talking about changing the risk

corridors. So it feels like they're pretty well covered against these various risks.

And I'm very much in favor of thinking about the reinsurance and the adequacy of the risk adjusters as one piece because they're tools to address the same issues. And I don't think we need to think about deploying them to deal with the big-bucket changes that can be addressed through some of those other policies.

DR. CROSSON: Alice.

DR. COOMBS: So I like the prix fixe menu. I just have problems with one aspect.

DR. BAICKER: Would you want a substitution? There's an up-charge for that.

[Laughter]

DR. COOMBS: Well, so for the reinsurance of 20 percent and the discussion around the incentive to take care of very sick people, I just question whether or not 20 percent is that right mark for that to happen.

First of all, the paper was really, really incredible because it explained so many different things. And I think that from what I assume in the paper is that the premiums are going to be readjusted to deal more

accurately, which is what they should be doing currently. So that part I have no problem with.

But the preferred pharmacy networks -- taking the LIS and subjecting them to this whole differentiation with the now multiple generic copays for the preferred generic versus the nonpreferred generic, and then now the preferred pharmacy network, I think it could be problematic for this very group, this population, in terms of just understanding that although there are low-income subsidies or other things, there may be barriers for them to be fully participatory with the preferred pharmacy network.

So that would be problematic for me, but the prix fixe menu I think at $35 is good.

DR. CROSSON: So, I mean, I think that's a good point. I mean, there are travel problems for people of low income, for example.

As we work this through, can we look at this issue in the commercial world? Is this possible to do? The impact on Part B recipients outside of Medicare created by the tiered pharmacy process, is that information --

DR. SCHMIDT: You mean the extent to which non-Medicare plans are using tiered networks?

DR. CROSSON: Well, yeah. And maybe I'm asking something that's impossible, but to the extent to which that's a problem for their patients or members or whatever you want to call them.

DR. SCHMIDT: Whether there are access issues.

DR. CROSSON: Yes, access issues.

DR. SCHMIDT: And we can also bring -- I think, was it last year CMS was looking at the beneficiary access with respect to these preferred networks? And we can bring some of that work before you.

DR. CROSSON: Right. So we can get some more information on that.

DR. MILLER: And I think at least some of that, if I'm remembering when we were talking about it at that point in time, is you can say you can use this -- for example, you can use this tool, but there are, like there are with network requirements now, certain requirements about how far --

DR. CROSSON: How far.

DR. MILLER: -- somebody has to travel and that type of thing.

And we were talking about a bit of that. I'm not

sure we had real specifics, but we were talking about a bit of that.

Am I getting a nod, or what am I getting? A yes? You're doing that poker face thing.

MS. SUZUKI: We also commented in the letter about maybe there should be a standard for the narrower preferred pharmacies to ensure that most people have access

DR. MILLER: Right. That's where I was thinking about it. We can bring some stuff back, and we might be able to have an adjustment to the policy that could potentially address your concern.

DR. CROSSON: Sorry. Shinobu, a standard in terms of travel time? A standard in what?

MS. SUZUKI: Just travel time, distance.

DR. HOADLEY: I mean, current law says that -- or current CMS policy has a time and distance standard for your overall pharmacy network, but that same standard does not apply to the inner part of the network, the preferred pharmacy network. So those can fail to meet that standard, and what CMS found was that for some plans they did not meet that within their smaller network. So that's where that issue comes up.

DR. MILLER: And then that's where we call for an adjustment.

DR. SCHMIDT: And that was mostly in urban areas if I remember correctly.

DR. HOADLEY: It's sort of the WalMart phenomenon. Some of the plans went strictly with WalMarts, and you've got a lot of big cities where there's no WalMart in the city. Now that's changing as well. But if they go with a particular chain and the chain is not well-represented in certain areas, that's kind of what happens.

DR. CROSSON: Okay. Additional? Is that a finger or a hand? Sorry, Jon.

Sorry. Go ahead, Rita, and then Jon.

DR. REDBERG: It's related to sharing risk but not what we talked about, but just as we're closing. Perhaps in the future I'm wondering if we've considered looking at fraud in the Part D plans.

And I mention it only because I happened to be talking to a pharmacy benefit manager who works with both commercial plans and Medicare Part D plans, and he was telling me that there's a lot less fraud detection going on in the Medicare Part D plans. There was a particular

instance he told me about someone who was getting their 30-day medicine refilled every few days, saying they had lost the prescription, but they were for high street-value drugs, where after a few months of that it seemed someone should be looking into it. And he said it took years in the Medicare plan to get anyone to address it, where in a commercial plan...

And I don't know if that is a one-off case or something more common, but it seems that with particularly everything else we're looking at, that could be driving up costs as well.

DR. CROSSON: Okay, Jon.

DR. CHRISTIANSON: Yeah, I think that street-value issue is going to be interesting for other drugs we don't think about now because when you talk about $80,000 or $90,000 for a drug, and if you don't do a 2-week but you do a whole course of treatment, there is a resale value to that. But that wasn't what I was going to say.

Jack, I think, kind of convinced me or got me moving towards thinking that having an out-of-pocket cap for beneficiaries in terms of drug spending is -- there's plenty of precedent for that, and it's not a bad idea. But

we didn't talk about it. So in the future will we be talking about, I guess, what the cost of that is, incremental cost of that, and do we need to find other places then, as is our habit, to try to figure out where to cover that cost to Medicare?

And then I guess the last thing is -- this is really naive, but if I were a taxpayer and subsidizing this program to the extent taxpayers do, and somebody said, here are two identical drugs, they're absolutely identical drugs, one has a different name than the other, and it's okay with Medicare that you get to choose the drug that's the higher cost with the different name, and we'll pay part of that -- that wouldn't compute to me as a taxpayer, I guess, but maybe that's just naive. Maybe there aren't many drugs where the generic is identical to the brand.

SPEAKER: There are a lot.

DR. CHRISTIANSON: We're continuing to say that's okay with this approach, and that just continues to bother me.

DR. CROSSON: Okay. This was a good discussion and an excellent presentation.

So the plan here is to take the input that you

have given us, all of which was very good, come back in March with a revised package. There will still be some opportunity then to work on it again and make suggestions. And then the idea is to bring it back in April for a vote for the series. I would say again, if possible, a package of recommendations which we would vote on as a package after having deliberated in March and April. And then, making the chapter in June, as we've mentioned before, both comprehensive in terms of the information presented, which will be broader than our areas of recommendation, but also will contain our recommendations on Part D and Part B depending upon our success after lunch.

Okay. Thank you, Rachel and Shinobu.

Now we have an opportunity for public comment. So I'd ask any individuals in the audience who would like to make a comment at this point to come up to the microphone so I can see how many of you there are.

Assuming my microphone is working, I see none. So we are adjourned until 12:45.

[Whereupon, at 11:47 a.m., the meeting was recessed, to reconvene at 12:45 p.m. this same day.]

AFTERNOON SESSION

[12:49 p.m.]

DR. CROSSON: Okay. It's time to start the afternoon session. We're going to be discussing Part B drug payment issues once again, and as I mentioned this morning at the beginning of this morning's session, we're coming back to a set of issues we've talked about before. And our intention here is to try to sharpen our focus so that later in MedPAC's term, we can get to some specific recommendations, hopefully by March, discuss those again, with the potential for a final recommendation and vote in April and inclusion into the June chapter.

So we've got Kim, Ariel, and Dan, and who is going to begin the discussion? Kim?

MS. NEUMAN: Good afternoon. We are going to continue our discussion of two Part B drug issues that we talked about last cycle and that were included in a chapter in the June 2015 report.

The first issue relates to the payment formula for Part B drugs, which is the average sales price plus 6 percent. The second issue relates to payment for Part B drugs in 340B hospitals.

So, today, our presentation will go as follows. First, I will review background on Part B drugs and the average sales price payment system, and then I'll present some policy options that would alter the ASP payment formula to include a flat fee add-on. Finally, I'll touch on some other issues relevant to Part B drug payment policy.

Then Ariel and Dan will discuss background on the 340B drug pricing program and discounts, and then present policy options concerning payment for Part B drugs in 340B hospitals.

Before we begin, we would like to thank Joan Sokolovsky, Nancy Ray, Rachel Schmidt, and Shinobu Suzuki for their contributions to this work.

In 2014, Medicare spent more than $20 billion on Part B-covered drugs. Most Part B drugs are infused or injected in physician offices or hospital outpatient departments. This includes expensive biologics and drugs for conditions like cancer, rheumatoid arthritis, and macular degeneration, as well some more commonly used inexpensive products like corticosteroids and vitamin B12, for example.

Part B also covers a limited set of drugs furnished by DME suppliers and pharmacies, such as inhalation drugs and immunosuppressives.

Medicare pays providers for most Part B drugs at a prospective rate equal to 106 percent of the average sales price, often referred to as ASP+6. Note that this ASP+6 payment is for the drug. Medicare pays makes an additional, separate payment to the provider for administering the drug under the physician fee schedule or the outpatient prospective payment system.

As you'll recall, a drug's ASP is the average price realized by the manufacturer based on sales to all purchasers, with some exceptions, net of rebates, discounts, and other price concessions. The price an individual provider pays may differ from ASP; for example, due to price variation across purchasers or other reasons.

As we've discussed previously, concern has been expressed by Commissioners and stakeholders that the 6 percent add-on to ASP gives providers a financial incentive to prescribe higher-priced drugs, although few studies exist looking at whether the 6 percent add-on is influencing prescribing patterns.

Last spring, we explored some alternatives to the 6 percent add-on that incorporate a flat fee as a way to reduce the potential incentives for use of higher-priced drugs. Building on that work today, we have developed two policy options that are alternatives to the 6 percent add-on. Both are estimated to be budget neutral to 106 percent of ASP based on 2014 claims data and assuming no utilization changes.

The first option is 102.5 percent of ASP plus about $17 per drug administered per day. You will notice that this first option looks like an option from last spring but has a higher flat fee. This is largely because we moved from using 2013 claims data to 2014 claims data for the basis of budget neutrality.

The second option is 104 percent of ASP plus just under $10 per drug administered per day. This is like option 1, except we retain more of the percent add-on and therefore have a smaller fixed fee.

A couple other things of note. We applied this model to drugs administered in physician offices and outpatient hospitals. We address the small group of Part B drugs furnished by DME suppliers and pharmacy suppliers

separately later in the presentation.

Also, 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 the two options. The price of the drug, as measured by the ASP per administration, is in the first column.

Now, looking at the first line, we have the example of a low-priced drug with an ASP per administration of $10. You can see that under current policy, that drug is paid $10.60. Medicare's payment for this drug would increase under the two policy options. The payment would be about $27 under option 1 and $20 under option 2.

Now looking at the last line in the chart, we have an example of high-priced drug with an ASP per administration of $5,000. Under current policy, this drug would be paid $5,300. Under options 1 and 2, it would be paid less, $5,142 under option 1 and $5,210 under option 2.

The last two columns on the line gives you a sense of how close these new payment amounts are getting to ASP. For this 5,000 drug, option 1 is equates to about

102.8 percent of ASP, and option 2 equates to about 104.2 percent of ASP.

And one last point, as I mentioned before, all of these estimates are based on pre-sequester payment rates.

As we saw on the last slide, both policy options would increase add-on payments for low-priced drugs and decrease add-on payments for high-priced drugs. Overall, these changes may increase the likelihood that a provider would substitute a low-priced drugs for a high-priced drugs where therapeutic alternatives exist.

Since these polices reduce add-on payments for very expensive drugs, it is possible that small practices may have difficulty purchasing very expensive drugs at the Medicare payment rates. But this would depend on how much the add-ons are reduced for expensive drugs and also how manufacturers would respond to Medicare payment changes. For example, when Medicare moved to the ASP payment system in 2005, there is some evidence that price variation across purchasers shrunk. It's possible something similar could happen with these policy options.

Like any payment changes, there may be opportunities for gaming with a flat add-on that Medicare

would want to monitor for; for example, monitoring to ensure providers do not respond to a flat-add-on by providing drugs in smaller, more frequent doses, or by overusing low-priced drugs.

These policy options would redistribute revenues across providers. A flat fee add-on increases payments to physicians overall and decreases payments to hospitals. Among physicians, those specialties that tend to rely on an inexpensive mix of drugs, like primary care, would see an increase in their Part B drug revenues. Specialists that tend to rely on expensive drugs, like oncologists, rheumatologists, and ophthalmologists, would see a decrease in their Part B drug revenues.

To illustrate this, you can see on the slide how Part B drug revenues change for the various types of providers under option 2.

The effect of these policy options expressed as a percent of a provider's total Medicare revenues for all services is, of course, much smaller, and that is shown in your paper.

In addition to these policy options, your mailing materials included information on a couple other topics

relevant to Part B drug payment policy. I will touch on these briefly now and would be glad to discuss more on question.

First, there is the issue of the dispensing and supplying fees that Medicare Part B pays to pharmacies and other suppliers for inhalation drugs; and immunosuppressives, oral anticancer, and oral antiemetic drugs. These fees are on top of Medicare's ASP+6 payment. And the OIG reports that Medicare is paying substantially more for dispensing fees than Part D or Medicaid.

Next, we have information on two structural approaches that some advocate for as ways to address concerns about providers' incentives for Part B drugs. First is a drug competitive acquisition program. Under this kind of approach, the Medicare fee-for-service program would pay a competitively selected vendor to supply Part B drugs to physicians rather than pay the physicians directly for the drugs.

Per the Medicare Modernization Act, Medicare implemented a voluntary program like this from 2006 through 2008, but the program was suspended. Physician uptake of the program was low, and Medicare wound up paying more than

ASP+6 to the vendor.

Another structural approach would be to shift coverage of Part B drugs to Part D. The financial effects on the program and beneficiaries go in several directions. From a logistical standpoint, it would be complicated to have Part D pay for drugs administered in physician offices and outpatient hospitals, but it might be easier to do so for inhalation drugs, immunosuppressive drugs, and other oral Part B drugs, since these drugs are commonly furnished by pharmacies.

So now I will turn it over to Ariel and Dan to discuss 340B.

MR. WINTER: We discussed the 340B program in prior meetings and in two reports earlier this year, in May and in June. So I'll start with a brief overview.

The 340B program allows certain hospitals and other health care providers, known as covered entities, to obtain discounted prices on covered outpatient drugs from manufacturers. Covered outpatient drugs include prescription drugs and biologics, other than vaccines.

Covered entities include disproportionate share hospitals, critical access hospitals, other types of

hospitals, and clinics that receive certain federal grants from HHS.

The discounts that providers receive on drugs are based on the ceiling price. This is the maximum price a manufacturer can charge for an outpatient drug under 340B.

As we described in our June report, this program has grown rapidly since 2005, both in terms of spending on outpatient drugs and the number of covered entities.

Medicare Part B pays for many 340B drugs provided to beneficiaries. Under the outpatient PPS, Medicare pays same rates for drugs to 340B and non-340B hospitals, even though 340B hospitals can buy outpatient drugs at a substantial discount.

Spending by Medicare and beneficiaries for Part B drugs at 340B hospitals that are paid under the outpatient PPS grew from $0.5 billion in 2004 to $3.8 billion in 2014.

340B hospitals can generate revenue from Part B drugs because the Medicare payments they receive for the drugs exceed the discounted prices they pay.

The 340B statute does not restrict how revenue generated through the program can be used. Therefore, hospitals can use these funds for any purpose, such as

expanding the number of patients served, increasing their scope of services, investing in capital, or covering administrative costs. The statute does not require hospitals to track or report how they use revenue from the 340B program.

In our June report, we estimated the discount that 340B hospitals receive on outpatient drugs. We have since updated this estimate using data from 2014. I won't review the method in detail here, but it's covered in your paper and the June report.

The basic equation is that the discount equals ASP minus the ceiling price. Because much of the data used to calculate ceiling prices are confidential, we are not able to precisely calculate these prices. Therefore, our estimate understates the discount; in other words, the actual discount is probably higher. We estimate that average discount was at least 22.7 percent of ASP in 2014.

Next, Dan will talk about the net savings on Part B drugs received by 340B hospitals.

MR. ZABINSKI: We found that in 2014 that 340B hospitals received $3.8 billion in Medicare payments for Part B drugs, and using the formula for drug discounts that

Ariel just covered, we also estimate that 340B hospitals paid no more than $2.8 billion to acquire those drugs, and this is an upper bound on their acquisition cost.

The receipt of the $3.8 billion in revenue minus an upper bound of $2.8 billion for acquisition costs indicates that 340B hospitals had net savings of at least $1 billion on Part B drugs in 2014, and these net savings were 1.2 percent of their overall Medicare revenue for 340B hospitals and 4.3 percent of their Medicare OPD revenue.

And for most categories of hospitals, net savings as a share of overall Medicare was close to the overall average of 1.2 percent. Net savings as a share of overall Medicare revenue was lowest among rural hospitals at .9 percent and highest among major teaching hospitals at 1.4 percent.

In our June 2015 report, we raised the issue of whether Medicare payment rates for Part B drugs should be lower than ASP+6 percent for drugs obtained at 340B prices by 340B hospitals. The lower payment rates in 340B hospitals would allow Medicare and beneficiaries to share in the discounts of the 340B program. However, reducing the payment rates would obviously reduce hospitals' revenue

from the 340B program, so policymakers may want to limit any reductions in payments so that these hospitals can retain a share of the revenue from the Part B drugs.

Next.

And for today, we have considered three options for reducing Part B payment rates for 340B drugs, ensuring the savings with Medicare and beneficiaries. In all three options, the Part B payment rates would continue to include the add-on of 6 percent of ASP.

In option 1, payment rates for each drug would be reduced by 22.7 percent of ASP, which is our lower-bound estimate of the average discount that hospitals receive on 340B drugs. The savings would be shared by Medicare and beneficiaries, where Medicare would get about 80 percent of the savings and beneficiaries would get the remaining 20 percent because those are the shares of the current payment rates that the two are responsible for.

Under option 2, payment rates for each drug would be reduced by 10 percent of ASP. We chose 10 percent because it's approximately half of the full discount received by 340B hospitals. Once again, these savings would be shared by Medicare and beneficiaries.

Under option 3, payment rates would be reduced by 22.7 percent of the current cost-sharing amount for each drug. Another way to look at this is the savings is equal to the amount that beneficiaries save under option 1. In this case, beneficiaries would get all the savings, and payments by Medicare would not change from current levels.

To summarize this, option 1 takes the full discount out of the payment rates for 340B hospitals, option 2 takes about half of the discount, and option 3 takes the cost-sharing portion of the full discount.

In this diagram, we show how current policy and the three options work for a given drug that has an ASP of $100. In the first column, we show current policy, where payment to a hospital is the $100 ASP -- and that's the red portion -- plus the 6 percent add-on, which is the yellow portion in the first column. This results in a payment to the hospital of $106.

The second column illustrates option 1. The red portion is smaller than in the first column because we've removed 22.7 percent of the ASP from the hospital's payment and shared it with the program, which is the green portion, and the beneficiaries, which is the light blue portion.

Payment to the hospital is now the smaller red portion combined with the 6 percent add-on, which would result in a payment to the hospital of $83.30.

The third column illustrates option 2. The red bar here is higher than under option 1 because now we've removed only 10% of the ASP from the hospital's payment and shared that with the program, once again the green portion, and the beneficiaries, which is the blue portion. And in this situation, payment to the hospital is $96.

The final column illustrates option 3. Here, we've moved 22.7 percent of the cost sharing -- from the red bar -- which is 4.5 percent of the ASP, and we removed that from the hospital's payment and shared it with the beneficiaries, which is the blue portion. Here, the payment to the hospital would be $101.50.

On this table, we show the estimated savings to Medicare and beneficiaries under the three options. For options 1 and 2, combined savings are $830 million and $365 million, respectively. Under these two options, Medicare gets 80 percent of the savings, and beneficiaries get about 20 percent.

Note that early on slide 13, we said that total

savings in the 340B program is $1 billion, while here we say option 1 has total savings of $830 million. The difference is that the $1 billion in total savings to 340B hospitals on slide 13 includes the 6 percent add-on, while the $830 million in savings to the program and beneficiaries on this slide does not include the 6 percent add-on because that stays with the hospitals.

Option 3 is different from the other two because all the savings goes to beneficiaries' cost sharing, and the program gets no savings, but note that the savings in cost sharing is the same in option 1 and option 2 at $150 million, and this was by design.

DR. MILLER: You said 1 --

Next. What's that? Oh, 1 and 3. Oh, did I misspeak?

DR. MILLER: Yeah.

MR. ZABINSKI: Okay, 1 and 3. Yeah.

As part of your discussion, please let us know any clarifications we can provide. Also, let us know of any additional information you would like.

Finally, we seek reactions to the options for changing the ASP payment formula and the other issues that

Kim talked about and also reactions to the options for payment for Part B drugs in 340B hospitals that Ariel and I talked about.

And now we turn things over to Jay and the Commissioners.

DR. CROSSON: Thanks very much. We're going to do clarifying questions. I am going to start with two myself.

So on slide 17, these are one year savings; correct?

DR. ZABINSKI: Yes.

DR. CROSSON: So 10-year savings would be some multiple of that. Okay.

And the other one is Kim, I might ask you, if you would, to expand a little bit on the issue of the fees paid to suppliers and the dispensing fee piece of this. We had some discussion of that in the pre-reading we had, but less here. And I think if you could go over a little bit of that, as well as the numbers, that would be helpful.

MS. NEUMAN: So, Medicare pays for certain drugs that are furnished by DME suppliers and pharmacies. So inhalation drugs, immunosuppressives for Medicare covered

transplants, certain oral anti-emetics and oral anticancer drugs. And when these drugs are provided by these pharmacies, Medicare pays ASP+6 percent and, in addition, pays a dispensing or supplying fee to the supplier.

The fees are substantial. The inhalation drug dispensing fee is $33 per 30-day supply of drugs or $66 per 90-day supply of drugs, no matter how many drugs are in that supply. And then there's a higher fee for the very first one in a beneficiary's lifetime.

And then with the supplying fees, it's $24 per 30-day prescription and $16 for each subsequent prescription in that 30-day period and then again a higher fee for the first immunosuppressive prescription after a transplant.

The OIG has looked at what other payers pay, Medicare Part D and Medicaid, and found that they are paying less than $5 in dispensing fees for these same kinds of drugs.

DR. CROSSON: Thanks very much.

So let's see hands for clarifying questions? We'll start down this way. Cori.

MS. UCCELLO: So on slide 6, trying to think

through maybe unintended consequences of this, making sure to monitor whether the flat add-on doesn't lead to more frequent dosing.

The proposals are per drug per day; right? So it's not just -- you wouldn't be splitting things up to multiple times a day. So how often is it that something is prescribed that's kind of less frequently than a day, that then would become more frequent? Does that make sense?

MS. NEUMAN: That's, I think, a clinical question. Some of you might be better positioned to answer that than I am.

The concern, just in general, would be if you have the choice of bringing someone back every couple weeks versus every week, would that affect your decision making? And I think, you can see in the options, some of the fees are bigger than options and it's bringing someone back into the office. So would that level of flat fee really be worth it to do something like that, would have to be thought through.

DR. CROSSON: Any clinicians want to weigh in on that? I certainly don't. Alice.

DR. COOMBS: I'll take a crack at it. It's not

just bringing them in, and I said this the last time we talked about whether it's necessary to be monitoring at the same time. There might be other monitoring things that you're doing simultaneously with the frequency of the visit.

So for instance, new oral anticoagulants, if there was some kind of restriction on that, you might use it as an opportunity -- because there's no laboratory that you would use in that case. But other drugs you might use as an opportunity to do other things. So you might have increase in the clinical services because of the frequency of the visits that would be necessary. So it might be a double effect.

DR. BAICKER: But are there drugs -- how many drugs are there where there's an option to do it once every week versus once every two weeks and either one would be okay? And this payment tweak would push towards half as much every week instead of twice as much every two weeks?

Or are there just very few drugs where you've got the option of varying frequency and dosage?

DR. COOMBS: I think this is an opportunity for telemedicine, but you know, with comorbid conditions you

could see that people might want to follow up say a person who is a brittle diabetic, who has a complex history with other comorbid conditions, that you might see an increase in another effect in terms of clinical visits in conjunction with that.

But I think that the tendency would probably not be to increase because there's usually saturation within the clinical sites in terms of, you know, you have a schedule that's fixed and, you know, you're bringing someone in solely for a renewal prescription and that becomes an issue with how busy the clinical side is.

DR. CROSSON: So I --

DR. REDBERG: So there is an opportunity to vary dosing often. Because you're looking at total dose daily or whatever.

DR. CROSSON: Right. But I mean, since we always underestimate the potential for gaming inherent in any payment system, I say this with some hesitation. But it doesn't seem like this one jumps out at you as a big risk.

DR. SAMITT: And I'd say that when you look at actually what the value would be of the fixed amount that would be recurring if you were to change the frequency of

the dosing, I'm not sure it's worth gaming the system for what this amounts to, at least in the analysis as shown.

So again, you're right. You never want to underestimate the potential of gaming, but in the scope of things it just doesn't seem that it's worth gaming.

DR. HOADLEY: And it's just important to remember, these are the physician-administered drugs we're talking about. So these are not just handing somebody a pill and then a question of maybe monitoring that. But this is, you know, an infusion in most cases or an injection.

DR. CROSSON: Clarifying questions coming up this way? Jack.

DR. HOADLEY: So on slide 5, an then it sort of plays out through the next couple of discussions, the impact at the different levels of cost of the drugs is obviously one of the things we're trying to play out here.

What would be useful to me, and I don't know if you have this kind of information, is how many of the drugs that we're talking about on the Part B side are in that $10 or lower kind of range? And how many are up there in the more $5,000?

I mean, obviously as a dollar value, most of the game is in the expensive drugs. But how much is in that low end? And what kind of drugs are we talking about in that end?

MS. NEUMAN: So in Table 2 in your materials, there's a chart that shows you the distribution of drug administrations by the ASP+6 payment per day for that drug. And so you can see that lots of the administrations that are going on are very inexpensive, a little under 50 percent are less than $10. Now we're talking about things like corticosteroids, vitamin B12, saline, there's a few others.

So that's where there's a lot of administrations happening, but the dollars are very, very, very small.

And then the dollars are concentrated among a small group of drugs that make up a very small share of the administrations but are, you know, $1,000, $2,000, $5,000 a shot.

DR. HOADLEY: Thank you. I had missed that table when I was reading the paper. Yes, I think it's helpful to think about what those are and clearly there is a lot of volume there as we think about this.

My other question was on the 340B and it sort of relates to the impact on slide 13. And I guess part of what I was trying to think about was impact by sort of type of hospital in terms of safety net. Obviously, DSH is one of the criteria to get into the 340B. But it would just be kind of a sense of among DSH hospitals what would be the impact? I don't know quite what the right way to divide the category but it would be interesting to see the impact along some kind of line so we kind of get a sense of what's going on in that sector?

DR. ZABINSKI: Page 35 of the paper has got a table that shows the revenue, acquisition costs, net savings. I think you were referring to the second full bullet on this slide?

DR. HOADLEY: Right.

DR. ZABINSKI: We've done analysis -- we didn't have the information to do that stuff in time to put it in the paper, but we've got it now. Most of the categories that we looked at, which include urban versus rural, major teaching, other teaching, non-teaching, government-owned versus other non profit. I looked at hospitals by size. I think that's about it.

Most of them were around the 1.2 percent average. The low was the rural hospitals, they were at 0.9, and the major teaching were at 1.4. Other ones, my recollection at least is they're quite close to the 1.2 percent.

DR. HOADLEY: And if you did the percent for just say the DSH hospitals, what kind of percent would we talking about there?

DR. ZABINSKI: Well, there's such a big share of the whole thing I would think that that would be around 1.2 percent. They're the tail that wags the dog here. They're the big player.

DR. HOADLEY: I think that would just be an interest, to get that kind of a percentage to see -- I mean, it seems like it would have to be somewhat higher than that actually, to get the 1.2 on the average.

DR. MILLER: Yeah, except that the revenue basis, all the revenue is running through the DSH hospitals. So that's what's driving the average.

DR. HOADLEY: Okay.

DR. MILLER: That's what he's saying.

DR. HOADLEY: Because the other ones are the small hospitals?

DR. MILLER: Let me just make -- that's what you're saying; right?

DR. ZABINSKI: Yes.

DR. HOADLEY: And that's because most of the other 340B hospitals are more the small, rural categories?

DR. MILLER: It may be that but I think the point that Dan is making is you tend to -- and everybody tends to think about these impacts, teaching, non-teaching, DSH, non-DSH. And DSH are these many of all of the hospitals.

But here, when you think about it in terms of money, all of the money is running through the DSH. I mean, virtually all of it.

DR. HOADLEY: Virtually all.

DR. MILLER: The table that Dan is referring to on page 35, I mean it's very small amounts not running through the DSH. So the DSH hospitals define the mean. And I think he's saying that's going to be 1.2.

DR. HOADLEY: Okay. Thank you, that helps.

DR. CROSSON: Clarifying questions. Alice.

DR. COOMBS: So I had a question about how constant is the discount that 340B gives? Is that something that we can assume that it doesn't fluctuate from

year to year?

DR. ZABINSKI: Well, we've done an analysis. This one is based on 2014. We did one for the June report that was based on 2013 data. The discount was 22.5 percent using 2013 data and 22.7 percent on the 2014 data. So that's an indication of some consistency, I think.

Most of these drugs -- like the discount rate for most of the drugs is 23.1 percent. So it's going to be -- I think it's going to stay pretty consistent over time.

MR. WINTER: There are two aspects to the discount that we don't have information on, which are the best price -- which could vary from year to year, we don't know. And then the average manufacturer price. We are using ASP as a proxy for average manufacturer price and we believe ASP is usually lower than AMP. But AMP could fluctuate more than ASP.

And there's also an inflation rebate that's a portion of the actual discount that we have no information on. So that could also be fluctuating. And that basically provides a larger discount or rebate if the price of the drug is increasing faster than inflation as measured by AMP.

So there are factors that we have no information on so it's hard for us to judge how much it fluctuates year to year. The estimate that we did is based on proxies and it's an approximation of the discount but it's not the actual discount, if that helps.

DR. COOMBS: And there's absolutely no institution where you have a peek into what it really looks like or can use it as a proxy?

MR. WINTER: Well, we've done the best we can with the information that's publicly available. HRSA does have the ceiling prices but they're not allowed to share them publicly. They're allowed to share them with the covered entities but now with the general public or with us.

DR. CROSSON: Jon.

DR. CHRISTIANSON: I guess this is for Kim.

I was looking again at the table on page 5 of your handout. I know the table wasn't constructed for this purpose but one of the issues that you raised was the possible incentive to prescribe higher cost drugs when lower cost ones might be available because of the way this is set up. You get ASP+6 percent so you get 6 percent of a

higher cost drug.

So obviously, to me, it seems like in these examples imagined the $490 drug was the substitute for the $5,000 drug can -- you'd still have the incentive to use the $5,000 drug. You still make more money doing that.

So what I was wondering about is did you run any examples of where there were, in fact, commonly used -- common situations where there was a high cost drug and one that actually did substitute for it where this might come into play? So we could get more of a sense of whether this change would actually change the incentives very much?

I mean, as long as you're going to make more money prescribing the high cost drug than the low cost drug, you're going to continue to prescribe the high cost drug, I would assume. Does that make sense? Do you understand --

MS. NEUMAN: No, I hear your question.

So two things. One, there will still, as you point out, be a difference in the add-on for between a high cost drug and a low cost drug. It's only going to reduce the difference. It's not going to make it go away.

And then as far as the question about

substitutes, we don't have an analysis right now comparing the incentives for two drugs that are substitutes. We could think about doing that. There may be places -- I'm thinking about anti-emetics or other kinds of things, where we might be able to take an example that's pretty clear cut.

But then there's all these chemo regiments with multiple drug cocktails and all of that. And that's what a lot of the dollars are on. To sort of try to do the substitute analysis would be much more challenging.

DR. CHRISTIANSON: I understand. I'm just not clear in my mind whether -- I mean, as long as you can make an extra dollar doing something, you should have the incentive to do it. So you cut that down from $30 to $20 or something, you're still going to make more money.

So I guess I don't know how much any of these would -- in real life, any of these changes that we've proposed would actually affect a decision about whether to use a cheaper versus a more expensive drug. I don't have a feel for that from the examples, because they weren't set up to do that. I understand that.

DR. MILLER: Well, and I think part of the reason

you don’t see a ton of this in the literature -- and we’ve talked about this internally a bit, about there is this real logic of 6 percent of a bigger number is a bigger number so I’m going to do the more expensive drug.

But I think part of the reason you don’t see a ton of literature on this is precisely for what she said. A lot of this is cancer drugs and actually figuring out what the proper pairings are and what the incentives would be is fairly difficult and fairly case-by-case type of judgment. It’s really based more on the logic of what the payment system is -- how the payment system is constructed.

DR. BAICKER: And isn't there also a lot of uncertainty about what their -- when we talked last time about whether to bring it down to just 100 percent, then there was some information about the uncertainty about the actual acquisition costs of any given entity and not wanting to go too far for risk of making it unaffordable for some entities that weren’t getting the best pricing.

DR. CROSSON: Because this is the average sales price, not the -- and the distribution varies by drug.

DR. CHRISTIANSON: So my general point, I guess, is it’s still pretty muddy to me what the actual change of

incentives would be here, and what actual behavior response we might expect to see.

DR. BAICKER: Except that we know 2 percent is less than 6 percent.

[Laughter.]

DR. CHRISTIANSON: Something will probably be, on the margin, affected. Something will be affected on the margin. Whether it's worth the change to have something affected on the margin or not is not clear to me.

The other general comment on 340B, and this isn't clarification so much as just something to share with the Commission that really made me sit up. On page 28 of your report, we have hospitals in the 340B program accounted for 22 percent of Medicare spending on Part B drugs in 2004 and 48 percent in 2013. So half of Medicare spending on Part B drugs is going through this 340B program, which I went -- you know, I thought this was more of a technical issue than it is. It's not a technical issue. It's a lot of money.

So the implication in the way you presented that, to me, was that more hospitals are qualifying all the time -- at least they qualified under PPACA. And that's one of the reasons for the expansion.

But also, PPACA took away the DSH -- or we use the DSH funding for some of these hospitals. So being able to make money -- I will put it bluntly -- make money on Medicare to subsidize their operations becomes even more important and critical for these hospitals, given that they're not getting the DSH funds which was, in fact, designed to do that. So this is almost like a back door DSH payment to these hospitals, if I'm understanding it correctly.

So I guess I'm asking Ariel just to sort of react to that. Is that how you see it, or not?

MR. WINTER: We've not thought about it that way but we can go back and talk to our DSH experts, like Jeff, and think about that some more.

DR. MILLER: The thing I would say is what the PPACA did with DSH is it moved that dollar from a disproportionate share dollar to an uncompensated care dollar and then was to allocate on the basis of uncompensated care. And there's some overlap between a DSH hospital and an uncompensated care hospital but actually what was always kind of an awkward situation for years and years is they said well, DSH is for uncompensated care -- I

mean, different arguments for DSH are made at different points in time, depending on who's in the room. But sometimes it was for uncompensated care but the actual overlap between DSH and uncompensated care was not that high.

And then the other thing that's still going on -- and I'm looking at Jeff to make sure I get this right -- is they didn't convert to allocating on the basis of the uncompensated care. They're still allocating on the basis of kind of a DSH Medicaid type of formula. So how much the actual legislation is done, moved the money is -- and I'm looking at Jeff -- not so much.

DR. STENSLAND: [off microphone.] The pie shrunk.

DR. MILLER: Yeah but --

DR. STENSLAND: [off microphone - inaudible.]

DR. MILLER: The distribution stayed similar and even the shrunk is, you know, the rhetoric is it's gone away but the shrunk is more like 11 to nine, something like that, in round numbers.

DR. CROSSON: Sue.

MS. THOMPSON: Are we still on clarifying questions?

DR. CROSSON: We are, indeed.

MS. THOMPSON: By policy or otherwise, are there any other programs that exist that allow hospitals to purchase drugs at a discounted price other than the 340B program?

MR. WINTER: We can think about that some more. We can't think of any right now.

MS. THOMPSON: Okay. And then on page 17, kind of building off the question around the DSH hospitals, what was the thinking about taking -- and I think I know the answer, but I want to hear you say it. What was the thinking about removing the critical access hospitals from this information?

MS. NEUMAN: The reason they're not in there is because they're not paid ASP+6.

MS. THOMPSON: Okay. They're paid on cost.

MS. NEUMAN: Yeah.

MS. THOMPSON: Okay.

DR. CROSSON: Sue, are you done?

[No audible response.]

DR. CROSSON: All right. Clarifying questions? Kathy. Rita?

MS. BUTO: Just a couple -- oh, did you have one, Rita? Go ahead.

DR. CROSSON: We had a late hand there.

DR. REDBERG: I was just trying to find the place.

On page 39 of the mailing materials, the appendix that just specifies the type of eligible hospitals, it seems like for 340B, how did freestanding cancer hospitals get in that mix? It doesn't -- it looks like a different kind of entity that rural and DSH hospitals.

MR. WINTER: These were added by PPACA in 2010, and I believe there were only two freestanding cancer hospitals that are in -- how many?

MR. ZABINSKI: Three.

MR. WINTER: There are three. Breaking news! Three freestanding cancer hospitals in 340B out of, I think -- how many other? Eight?

MR. ZABINSKI: Eleven.

MR. WINTER: Eleven. Three out of 11.

DR. REDBERG: Do you know what was the rationale behind adding those?

MR. WINTER: We don't know the rationale on -- I

don't believe there was a conference report that explained it. I mean, you can talk to people who were involved in the legislation who might have insight, but we're not aware of why that category was added.

DR. REDBERG: And where are those three?

MR. ZABINSKI: I know one of them is the one in Florida. Whichever one that is, I don't know.

MR. WINTER: There's one in California.

MR. ZABINSKI: There's one in California. Okay.

And the other one might be MD Anderson, but I'm not certain.

DR. MILLER: But can certainly know --

DR. REDBERG: Thank you. It's a good thing it was.

[Laughter.]

DR. CROSSON: Kathy.

MS. BUTO: I have a question about -- there are a couple of materials. One was in the Tab A reading materials, and I think one was in the paper. I was trying to find it. I think it's on page 25, where we say that MA plans paid rates equivalent to ASP+7 to 13 percent for physicians and 14 to 32 percent for hospital OPDs. I'm

just curious about that and whether -- I know in MA plans and hospital DRGs, MA plans are able to choose the DRG payment rate. I think that's still true, and I wondered why they are paying higher amounts or higher rates than Medicare pays in its fee-for-service business. Do we have any idea?

MS. NEUMAN: So that provision that you're referencing with respect to inpatient and being able to refer back to that --

MS. BUTO: Yeah.

MS. NEUMAN: -- that doesn't exist relative to Part B drugs, and all I can tell you is sort of anecdotally when we've talked with a few plans, they say that hospitals won't accept lower rates. That's what we hear.

MS. BUTO: Well, it's also physicians according --

MS. NEUMAN: Right. Right.

MS. BUTO: They're also paying physicians more, so I guess physicians also won't accept lower rates.

DR. MILLER: Well, but some of that is the consolidation. So if the hospital either is employing physicians or physician practices are getting larger,

they're able to extract higher rates.

MS. BUTO: Yeah.

DR. MILLER: We've had this -- well, I'll leave it there.

MS. BUTO: Yeah.

Let me ask one other, just sort of Round 1 question. It has to do with the inhalation drugs in DME and the other drugs that are bundled with DME -- are not bundled with DME, I should say. This is ancient history, but I recall when I was at CMS, we realized that we had made a terrible mistake in actually not bundling that with the DME and somehow developing a combined payment rate. And I'm wondering, is that still by regulatory authority, or is that in statute now that the drugs have to be paid separately?

MS. NEUMAN: So the Medicare, when it established the ASP payment system, specifically put inhalation drugs under ASP+6 and did not allow them to go to competitive bidding. Under competitive bidding, there was that demo, and they got savings on the inhalation drugs, but not that substantial. And so I think the thinking was that they would do better on those drugs at ASP+6 than they would do

in some other approach.

MS. BUTO: Again, just to be clear, I wasn't talking about competitive bidding, just the drug. I was talking about a change that would actually bundle the cost of the drug into a combined payment with the DME.

MS. NEUMAN: And so it's not -- it is currently not permitted by statute. The drug has to be paid separately and at ASP+6.

DR. CROSSON: Clarifying questions? David.

DR. NERENZ: If we could just look quickly at slide 4, please, the first bullet.

Any of these changes that we're talking about would involve some cost of change, and they add some complexity, say, to the payment model. So, presumably, we do this to solve a problem. Are we solving a theoretical problem or a real problem? I'm curious. When you say few studies, can you give a couple examples of data on, say, overprescribing or inappropriate prescribing based on this 6 percent?

MS. NEUMAN: So there have been a couple of pieces of work that have sort of touched on this issue. One is a study by Jacobson and colleagues, done, looking at

lung cancer prescribing patterns right before and after the ASP payment system went into effect, and in that city, they found that crossing that threshold between before ASP and after ASP, that use of the most expensive lung cancer choice among the drugs went up. So that's one example.

Another that sometimes people point to is with the least costly alternative policies for prostate cancer drugs. When those were removed, we saw movement toward the more expensive prostate cancer drugs. But then, as Mark has said, this is a very hard thing to study and know when is financial incentives is causing behavior versus clinical decision-making and individual patient characteristics.

DR. MILLER: The reason you got those two studies is because there was a change in policy, and somebody had the insight to use that as a research design and go after it, and it's hard to do it in a static environment.

DR. CROSSON: Jon.

DR. CHRISTIANSON: So just to follow up, the size of that change, those changes in those studies, how did that compare to the size of the changes you're modeling here?

MS. NEUMAN: The size of the change of the

payment?

DR. CHRISTIANSON: I'm just trying to follow up what David said.

MS. NEUMAN: Yeah. No, no. I'm trying to do the math. I think I should get back to you on that point because we're talking about how much did payments change by going from AWP-based payment to ASP-based payment versus how much do payment changes go from 106 percent of ASP to these.

DR. CHRISTIANSON: That's fair. That's fair.

MS. NEUMAN: This is probably less, but depending on how expensive the drug, so we'd have to -- we could get back to you.

DR. CHRISTIANSON: So, yeah, I think the few studies are suggestive, but you're going to look at how applicable they might be when you take a close look at the size of the change, right? Is that what you're saying?

MS. NEUMAN: [Nods head.]

DR. CHRISTIANSON: Okay.

DR. CROSSON: Okay. So we're now going to move into -- I think movement towards a direction of perhaps sidling up to the notion of maybe we get to some

recommendations here.

As I looked at this one, again, we have multiple options on the table, all in the next 40 minutes: three potential options, including doing nothing with ASP; two for the supplier dispensing issue; and potentially four for 340B, including doing nothing. So that's nine.

Similar to this morning's discussion, but not similar, we have multiple issues on the table, but they're not necessarily interrelated in the way that the ones were this morning. So what I thought we would do, here again at some risk, is -- and, Kathy, I'm setting you up here, so be careful -- is to put up a straw-person for each one of these three areas, and the purpose being here to argue for or against the proposition. And the notion here is to try to streamline the discussion, which Kathy is going to lead. So there should be a slide appearing any minute, which I don't have a copy of.

So the argument here is that the starting place for discussion would be the smaller reduction in ASP, and the idea here is that, as has been raised here already, I think we have some concerns about moving too aggressively here, and the impact, as Kate described, on some of the

smaller practices, who are on one end of the distribution curve for actual purchase price. That's the logic there.

The logic for doing anything is that, in fact, we have -- we believe we have a problem identified, and whether it's theoretical or actual or a combination of both, I think is fair.

Although we haven't discussed it much, I think there's an argument to be made, given the size of the differential here, for reducing the Part B dispensing and supplying fees for supplier-furnished drugs down to the level paid in the commercial environment, if that's the proper way of describing it.

And then with respect to 340B, to take the middle course, if you will, and that is to reduce the payment rate by 10 percent. This is both to recoup excess payments for the Medicare program for the Treasury and also return money to the beneficiaries, and so that, we could use as a starting point for the discussion. And Kathy is going to kick it off.

MS. BUTO: So I think these three policy options would move us -- we talked about this issue enough that we seem to have at least some agreement, pending further data

analysis, the impact of some of these options, that the current ASP+6 percent does sort of drive toward the opposite of least costly alternative, which is sort of the most costly alternative.

And, in an effort to try to have a broad impact on that potential -- and I think Jon's point is important -- do we really know anything about what the movement would be if we were to move to something like this?

I think the 104 percent of ASP plus the flat fee is at least the beginning of a move to try to take some of that additional incentive out of there.

The second one, reducing the Part B dispensing and supplying fees, I think the paper was very compelling on that point, and I would agree with that. I would actually -- I liked your point -- and in the paper, we didn't talk about it -- about potentially moving those drugs to Part D, since they've essentially gotten through the pharmacy. I don't know whether we think that would actually increase costs, so I think that would be an important thing to know or at least get a sense from you as to whether that's a good idea or whether we ought to just leave well enough alone.

I personally would like to see them bundled, but it sounds like the statute is where that lies, and it's very difficult to change the statute when it comes to something like this. I'm not sure you could ever get it done.

The third one, which is kind of the middle option, I guess, between taking all of the discount back to the federal government and for beneficiaries, I think it's reasonable because, at least in our earlier discussions, we've talked about recognizing the fact that Congress very deliberately wanted to subsidize the 340B hospitals with some -- you know, they recognized what they were doing, shall we say. And it could be that this is step one.

I think the other notion about the Affordable Care Act was that it would eventually begin to provide revenues from the formerly uninsured to hospitals, and that would be another way to compensate for what was formally disproportionate share. I don't think that's happening as quickly as everybody had hoped, but it could be that this is one step in that direction.

So bottom line is I'm comfortable with the recommendations or the options that the Chairman has laid

out.

I would like to see just more of what we've talked about already, about some of the impacts and potential impacts, before we really nail this down because I think we want to know what both we're recommending and what some of the unintended consequences might be.

DR. CROSSON: Kathy, I want to just make two quick points.

Jon, did you just raise your --

DR. CHRISTIANSON: I just have a question for Kathy.

DR. CROSSON: Go ahead on that.

DR. CHRISTIANSON: So Congress knew what they were doing your comment about that, so they knew what they were doing to the extent that they wanted to make -- they wanted to provide some financial relief for these hospitals by allowing them to buy drugs at a lower cost for Medicaid beneficiaries, or did they know that they -- did they know what they were doing in the sense of designing a program where Medicare would indirectly subsidize the hospitals? How do you see that?

MS. BUTO: Yeah. Actually, I didn't see it that

way.

DR. CHRISTIANSON: Okay.

MS. BUTO: I thought we should take the whole subsidy back or really not -- just as we don't subsidize Medicaid with Medicare rates, why are we subsidizing 340B hospitals? But I thought the previous longer discussion we had as a Commission was some general agreement around the table that Congress did seem to know that that was part of this, that by allowing -- not just expanding the number of hospitals, but allowing Medicare to pay at full payment, while hospitals were getting, in a sense, a much better deal, the Medicaid -- basically what amount to the Medicaid rates, that they knew there was going to be an implicit subsidy there for those hospitals.

DR. CHRISTIANSON: Okay. That's interesting. I wasn't sure that that was --

MS. BUTO: I thought that was in our previous discussion, but, Mark, you might --

DR. MILLER: There were differences of opinion. Some people interpreted it as this is what Congress intended. Some people said it's not clear.

And the other thing I just want to remind you

guys, and it doesn't -- I don't think I need to say it, but I'm going to say it, anyway. We frequently recommend things that we think the Congress should do, even if they have made laws going in different directions. So it's a useful marker to know what they were saying, but whether you want to stand by that marker, you're here for other purposes.

MS. BUTO: Right. And I assume we'll come back to discussing these when we're ready to finalize our recommendations, but I'd be much more inclined to say, if this were just me, let's start here, assess what the impact is, and potentially move to the full 22.5 percent or whatever it is. Yeah.

DR. CHRISTIANSON: I agree.

DR. CROSSON: I just want to make two points here. Number one, I've made it already, but just to be clear, unlike this morning's discussion, this is not a package. These are discrete items. We are just putting them up for discussion purposes.

The second one is just to remember that on the 340B issue that, depending on where we go, if there is an impact on hospital revenues as a consequence of this for

certain hospitals, as there will be, this is not the only tool that this Commission has to influence payments to hospitals, including certain types of hospitals.

So you want to start down at this end? David.

DR. NERENZ: I'm comfortable with the first two, and I have a couple concerns about the last one, although with the first one, I'll just say there's a little aesthetic issue that we have a, currently, simple thing that has one component. Now we add another one. We're kind of in this hybrid. I just would want to know that the problem is big enough to be worth moving in that direction, but the direction is fine.

In terms of the 340B, just three concerns I think are related, and they play off including something, Jay, you said and Kathy said. I did have the sense in our March discussion -- and I think it was eloquently captured by Glenn in his marks that closed that particular section -- that if we choose to go down this path, we do risk -- I think his phrase was "frustrating the intent of Congress" -- in establishing the program, and it does rest on this assumption that Congress knew and has continued to know during this whole time period that Medicare is not exempted

from the subsidy, let's call it.

And as, Mark, you said, we can choose to recommend something different, but at least I have a caution about that, just because they wanted in a context outside of Medicare to create this mechanism for safety net hospitals. So I would be concerned about that.

I also, just in terms of the impact, recognized that the amounts we're talking about -- and I know we're estimating it sort of like 1.2 percent of overall Medicare revenue on average -- that's in the range of what we talk about in December and January for the annual payment updates, and when we do that, we apply this filter of payment adequacy. And we're not applying that here. So I think we're talking about pretty big movements of lots of dollars in a domain where I think the last time we looked at it, the Medicare margins and the overall margins were negative, so just a little caution about that.

The third thing is we ought to anticipate what the responses would be if we did this. We don't know for sure. Some of the ones I think about would be negative or harmful in the sense that if you're talking about hospitals that, by and large, do not have positive margins, a cut of

2-, 3-, $4 million, whatever it would be at the individual hospital level, is going to be noticed, and it's going to be something. And we don't know what that something is, but at least we ought to be concerned. Does that mean shrinkage of charity care? Does that mean a shrinkage of community outreach and community benefit activities? Maybe. But it would be worth at least trying to find out what that might be.

So, all in all, I'm just concerned about this as a way to go, and I appreciate, Jay, your comment that there are other moving parts that we will discuss in the next couple of months about payment to hospitals, and it may be that an action like this could be compensated by a different upward action of some other kind, and the net result of that might be better.

But I end up being a little worried that if somehow our goal was to find $800,000 of Medicare savings, safety net hospitals wouldn't necessarily be the first place I'd go looking for that.

DR. CROSSON: Coming up this way. Craig.

DR. SAMITT: So a little different than David's perspective, I'm actually comfortable with the second and

the third, and I have some questions about the first, mostly because I don't quite understand what this change accomplishes.

So if the net cost to the program is ultimately going to be about the same -- we're essentially just replacing the 2 percent ASP with a fixed fee -- it doesn't save the program anything.

And I also question whether even a reduction from 6 percent to 4 percent would change prescribing patterns in terms of use of higher priced -- lower price versus higher price.

So it feels as if we're making a modest change that creates complexity without any advantage, and I guess I'd alternative say make no change at all or go further and go deeper, bring ASP down quite a bit more substantively and increase the fixed amount in a manner that really may change prescribing patterns. So that's the piece of this that I just don't fully understand why we would make that one change the way we're proposing it.

DR. CROSSON: Rita?

DR. REDBERG: I'll agree with what Craig said about preferring the second and the third and not the

first, and I just think I would like to go back and readdress bundling of payment.

We had talked in the past about -- at least for oncology drugs --

DR. CROSSON: Oncology drugs.

DR. REDBERG: -- which is a lot of the Part B expenditures, bundling, which to me makes a lot more sense, because I just -- I'm afraid we're again playing around with pieces that aren't really going to accomplish the purpose of ensuring value for what we're paying for. I mean, are we really accomplishing our goals with the 340B drug discount?

And the whole ASP seems to me kind of the same problems as a fee-for-service, when we talk on the physician payment side. We're just rewarding volume without looking at what we're paying for or value, and that's the way the bundled payment for actually more than oncology would make more sense to me.

DR. CROSSON: And that's a reasonable position.

I don't know that I was on the Commission for the whole discussion of bundling, but my sense was that it was a good discussion. But we were unable to come to a

conclusion. Is that fair?

DR. MILLER: Yeah. I was talking to him about this last night, and I just want to make a distinction. We had long conversations about bundling on post-acute-care-related hospital, that type of thing, and those had a hard time finding a landing point.

What we did agree in this instance is Nancy -- and I'm looking at her -- okay. And I got the nod that I needed. Nancy has taken the bundling piece for oncology and is looking at that, and we're staging that for a later meeting when we can bring it to the table, so that piece of bundling is not off the table.

Now, how determined it is and whether you guys settle on it and all the rest of it, that's a different question.

DR. CROSSON: So we'll keep it -- so this is in play. It's in play.

DR. MILLER: That's the --

DR. CROSSON: Yeah.

Kathy?

MS. BUTO: Just to follow up on Rita's point, I agree with Rita that bundling would be a more preferable

way to go, if we could figure out how to do it. I think that's the challenge here.

So the question I have is as little bit of timing. We're thinking that we'll move ahead with these issues that we've already talked about probably before we fully develop the bundling options. Am I getting that right, do you think? Because it's going to take us a while to figure out how to come up with recommendations in that area.

DR. CROSSON: What would be the timing of --

DR. MILLER: I think I'm inclined to agree with her in the following way. If you guys were to come to an understanding here and you look at these three things and you say you want to do X or Y or a little bit of X and a little less of Y, whatever, we would probably come back with draft recommendations, Jim, in March, and then you would vote in April, and we'd write it up in June.

Probably, what will be happening about that time is Nancy will be hitting the scene in either March or April with "Here's how you could think about bundling," and I guarantee you, it will be a complicated conversation. The notion of coming to a hard conclusion at that point would

surprise me.

DR. CROSSON: Jon.

DR. CHRISTIANSON: Just a quick comment. David, I think all of your comments are right on, so I'd agree with them all.

I think there's also the point of view that in the best of all possible worlds, we would have a general -- "we" meaning society, Congress -- would have a general discussion about how much we want to subsidize hospitals to keep them open and deliver high-quality care, and then we would come up with -- and then that would be a subsidy out of general tax revenue.

I think by doing it this way, we're disproportionately putting the burden of that subsidy on Medicare beneficiaries, and I'm not all that happy with that.

DR. NERENZ: And I agree with that. I see that also.

DR. CROSSON: Now, seven and a half years I've been on MedPAC, we've come at this issue, this generic issue, multiple times, which is there's some perturbation in the payment system, which was perhaps unintended or

intended, or intended at one level and now it's at another level. And it represents some sort of cross-subsidy, and the general argument is, isn't it better to remove that and deal with the issue directly? And this falls into that category. Sometimes, honestly, you can do that, and sometimes you can't.

Alice.

DR. COOMBS: While I support each one of these bullets, I am ambivalent because I don't know exactly what revenues are done -- what revenues are invested in, in terms of capital, versus patient outreach.

My strongest feeling is that I think the beneficiary should benefit from whatever savings, whatever is accrued here, so that's my strongest opinion there.

And I don't think we really know behind the scenes what is happening with the revenue that's generated from the 340B. That causes me pause, because how could you be very aggressive with the 22 percent or even the 20 percent? I think it's right, but I'm not sure.

DR. CROSSON: Kate.

DR. BAICKER: So I have to think that moving away from differentially subsidizing higher-cost drugs is the

right direction to be moving. I take Dave's point that if you're going to incur the complication of going to a flat fee plus an add-on, do you want to do it for just a scooch? Given the hazards of moving in that direction and some of the mixed feelings, I can understand the argument for doing a little and seeing how it goes before going all the way. So I can see arguments on both sides, but I have to think that reducing the marginal incentive to opt for the higher-cost drug has to be a move in the right direction.

As for the 340B, all the evidence we have about the scope of the problem that Jon brought up and evidence that this is being used in a way that was not necessarily originally intended and is not particularly well targeted makes it clear to me that something needs to be done.

Whether this is the best option, it's hard to know for sure. There are some other things we've talked about in the past that would have more of a flavor of targeting the patients rather than the entity delivering them. It strikes me that those are likely to be much more complicated, and then maybe this is just the most tractable way to move in that direction. But, in some sense, part of the problem is all of the patients who are going through

this now very broadly defined class of entities and that the targeting is just not so good, and while, of course, we want to ensure the presence of a robust safety net, this seems like -- the way we're doing it now, it seems like an awfully distortionary way to subsidize a particular group of patients and the providers who serve them.

So I feel like this can't be -- the way we're doing it right now can't be the right answer, but I understand that any of the solutions that are on the table have pluses and minuses.

DR. CROSSON: Thank you. Kate, I just put "distortionary" into my personal lexicon. I'm not sure I've ever used it before, but I like it.

[Laughter.]

DR. BAICKER: I recommend using it every day.

DR. NERENZ: Kate, I would have thought "scooch" is the more appropriate thing.

[Laughter.]

DR. NERENZ: But that's a technical term I would have used if I had known it.

DR. CROSSON: Jack.

DR. HOADLEY: So I'll start with the 340B. I

mean, I think I share a lot of what Kate just said. This doesn't feel like the right way to subsidize the safety net.

On the other hand, if we make this change, we are taking dollars out of those safety net institutions, and so there's at least in the short term, we're potentially doing harm there. So I think trying to think about how to do it, if that means we come back on the -- if we can bundle this with something we do on the update discussions, that's appropriately targeted. But I don't know. We typically have said we're making update recommendation in general, and here we're talking about a much more narrow set of hospitals.

And I wonder, for example, talking about, say, DSH more broadly as part of a hospital discussion is a much bigger topic than just what we tend to do in the update. So I guess I worry about -- even though it sort of says Medicare shouldn't be the engine that generates money for the safety net, we are where we are, and if so we make a subtraction, do we have an idea of where to go to put the other money back in? And if in the ideal world, that's not somewhere through Medicare, then it's kind of not our

jurisdiction. So that's what gives me pause in sort of going for this.

Certainly, if we go for it, doing it at the 10 percent level rather than the 22 -- or whatever the number is -- level makes sense, although I can probably find it interesting to think about just the copay side. That was something I hadn't thought about before this discussion. That concerns me that we're sort of doing that without sort of thinking through what the impact would be on those hospitals.

Going back up the list, on the supplier thing, I think I'm fine with the proposal here. I mean, like Kathy initially said, rethinking, switching this over to D or going with some kind of -- any of these changes are going to require -- I think even the supplier fee, I think requires statutory change, although I don't know that. I don't know if that was --

MS. NEUMAN: Supplier, the rate is set by CMS, so that wouldn't need to be -- if you wanted it reduced, that's under CMS's authority.

DR. HOADLEY: That one is regulated, okay. So that one could be done regulatorily.

DR. CROSSON: Oh, no. Now I have another word.

[Laughter.]

DR. CHRISTIANSON: Let's scratch that word. By regulation. To go to something like a bundle that Kathy was talking about or to go to Part D, either of those would require a statutory change, so they're sort of on the same page in terms of a bigger lift.

And while I think there's a lot of complexities on doing other parts of the Part B drugs through Part D, for reasons that are talked about in the paper, I think at least in this small set, it's at least a more reasonable possibility. But it is a bigger lift in general, and so I think this is maybe an okay way to go.

On the ASP, I guess when I've talked about these issues, I often think of this as a potential savings mechanism, and then that becomes part of the rationale. So I guess I'm wondering why we'd necessarily frame this as a budget-neutral policy as opposed to a savings.

Now, as an asterisk on that, we've sort of got the sequester in there cutting some of it, so we don't really have 106. We have something less than that, but we tend to put the sequester aside and say that's a separate

policy mechanism.

But it seems like maybe it's worth thinking about if we're going to do something like this, rather than do it on a budget-neutral basis, is get some savings out of it while making a small contribution towards changing the relative financial incentives.

I originally thought more in terms of the flat or more like an option 1. I hear some of the arguments for option 2, both in the sense of not disrupting as much and sort of the interesting impact on the low-cost drugs, and the latter part also makes me wonder, although this adds complexity. So, for that reason, I wouldn't like it. If you want to end up with some kind of hybrid where you treat the low-cost drugs differently than the high-cost drugs, but that starts to sound so complex, it scares me away pretty quickly.

I mean, this is the challenge we're trying to -- most on financial incentives for expensive drugs, we're not trying to -- we don't want to create something strange on the low end. But I do think at least if we're going to do something here, let's get some savings out of this while we go.

DR. BAICKER: Just a quick clarification. It's budget neutral only if no one changes behavior.

DR. HOADLEY: True. Right, right.

DR. CROSSON: Right.

DR. BAICKER: Whereas, if --

DR. MILLER: Right. But I'd take his comment as, if you do it, be direct about extracting.

DR. HOADLEY: And you may get both -- like if you want to 102 plus 980 or just to pick something, you would get the 2 percent savings sort of guaranteed -- well, never guaranteed because there's behavioral effects everywhere, but you'd potentially get the 2 plus whatever behavioral impact you have.

DR. CROSSON: Just on that note, I guess we don't know. We have no way of knowing the -- if we moved from 106 to 102 without the full flat fee or part of the flat fee, we don't really know what the distribution curve of actual acquisition costs are by practices; is that right?

MS. NEUMAN: Exactly.

DR. CROSSON: Is there any way to assess that between now and March?

MS. NEUMAN: Acquisition cost data is not -- is

not really available.

DR. CROSSON: Right. So I guess just -- and this is part of where we ended up, and it applies to your suggestion as well, Jack. I am concerned about a policy that we put in place and it ends up with 30 or 40 percent of practices, essentially put in the position of having to buy and administer the cost at a loss -- the drug at a loss. And I think it would be helpful to me to try to understand the implications of these choices with respect to that.

MS. BUTO: Jay, can I just add one other?

DR. CROSSON: Yeah.

MS. BUTO: Jack reminded me of something, and I should remember this, but I don't. Prompt-paid discounts are not counted in calculating ASP. Is that something we should think about or look at? If you include it, is it significant? Does it lower ASP considerably? Is there any reason why manufacturers wouldn't still try to get their drugs quickly or wholesalers wouldn't want the drugs quickly from manufacturers? I'm just trying to understand that because that may be an area -- and I may be picking on the wrong thing -- where they've explicitly excluded it,

but it might actually yield something.

MS. NEUMAN: So just to clarify and make sure I'm following -- so the prompt-pay discount right now is the discount the manufacturer pays to the wholesaler when the wholesaler pays quickly, and anecdotally, we hear that wholesalers generally do not share those discounts with the final purchasers.

So, when the manufacturer calculates their ASP, they have to take into account that prompt-pay discount. So let's say it was 1 percent. That prompt-pay discount will lower ASP by 1 percent, but that 1 percent discount, anecdotally, is generally not passed on to the providers.

So is your thought that we would want to take -- to not have them subtract it from ASP or --

DR. MILLER: I took her thought as if Jack was looking to lower ASP, does including the prompt-pay discount lower ASP, and I think you're saying it already has.

Kathy, I'm --

MS. NEUMAN: It already lowers it, yes.

DR. MILLER: Yeah. And I'm interpreting, Kathy. If that's not what you meant, then --

MS. BUTO: That is what I meant. I thought prompt-pay discounts were not counted in calculating ASP, but they are is what you're saying.

MS. NEUMAN: Yes. So it lowers ASP. Prompt-pay lowers ASP, but it does not lower AMP. This is a different policy.

DR. CROSSON: So, if I understand it, then the net effect of that is to further distance the -- for some practices, the actual acquisition cost from the ASP.

DR. MILLER: Right.

DR. CROSSON: is that right?

MS. BUTO: Yes. For some, yeah.

DR. CROSSON: By a percentage point or something.

MS. NEUMAN: We only have anecdotal information. People often say 1 to 2 percent, but there's no data to validate that.

MS. BUTO: And you also pointed out the wholesaler add-on does the same thing. It's an add-on, an additional amount that the purchaser may be paying that again is not reflected in the ASP.

MS. NEUMAN: And we think that --

MS. BUTO: So that goes the other way.

MS. NEUMAN: -- that affects low-price drugs, not as much the really expensive ones.

DR. CROSSON: Jack, on this?

DR. HOADLEY: Yeah. I was wondering. You probably don't know this either, but is there any sense whether the spread of acquisition prices is sort of proportional to the price of the drug? In other words, is it plus or minus percent, or is it more plus or minus flat amounts? And, obviously, we don't have data, so we can't answer it empirically, but do you get any sense that the acquisition price is likely to be 4 percentage points up on a thousand-dollar drug and 4 percentage points up on a $20 drug?

MS. NEUMAN: I don't think I can answer that right now. Let us see if we can --

DR. HOADLEY: But that might go to the same --

DR. MILLER: But, yeah, I do want to comment on that because this is the other thing I thought is important to say.

You know, the ASP is ultimately the product of a competitive set of prices, so the manufacturer is offering and practices are purchasing. If you were to do something

that Jack said, "Okay, I am going to do ASP+2 or ASP+3 or whatever you're saying," and people are saying, "What's the distribution of the data?" -- and the distribution at any point in time could be what it is. But if the manufacturer wants to keep selling, they have to decide what they're going to do. And around that average, in this instance, it's not so much moving the average, necessarily. It's moving the distribution around the average, meaning I'm going to tighten it up, plus or minus, in order to make sure the physician can purchase.

This is the thing I was leading up to, and I'm very unsure here. I thought a few years back, way early on when this started happening, we looked at this, and we thought there was some compression in the distribution.

MS. NEUMAN: Right. There's some evidence that there was some compression around the time that ASP went into place --

DR. MILLER: Yeah. And I'm not --

MS. NEUMAN: -- in response.

DR. MILLER: I don't mean to say that as, like, "Okay, no problem," but remember you have two moving parts here. If Medicare changes its percentage, the manufacturer

has to decide to respond or somehow take the fact that some practices are not going to be able to purchase their drug.

MS. BUTO: But, Mark, just to follow on that point, I think there was an old CBO study on best price, and when best price came in, there was -- I think maybe CBO expected, but some did not expect to see the compression on the commercial. So, in other words, drug prices flattened out everywhere because all those discounts and rebates and so on were being counted.

So one of the things, even though we're not -- it's not in our authority, that we should just kind of be aware of is whether what we do might actually have a negative spillover effect on drug pricing. So there isn't much differentiation, even for those who can't afford to purchase, so just something to think about.

I think CBO did a study, probably 10 years ago now.

DR. CROSSON: Okay. Let's move ahead and -- Mary.

DR. NAYLOR: I'll try to be brief.

Related to the first bullet, I would concur with

the sentiment that we shouldn't be doing anything in the form of a scooch but more to a savings.

I absolutely support the second, reducing Part B dispensing. It's applying fees.

On the third, I really am troubled by this -- I would move more toward option 1, over time, with a transition plan so that we can begin to think about the kind of other tools that are very transparent and targeted toward addressing issues related to safety net hospitals. But if we move with this proposal here, I would really like to see how the reduction in payment, even in the short term, if it is closer to 10 percent, that we could restore the 22.7 percent to the beneficiaries, as directly as part of that plan. It doesn't seem at all to me that we should be not responding to what is a discrepancy in terms of our beneficiaries, the ones we're serving.

DR. CROSSON: Cori.

MS. UCCELLO: I'm afraid I'm less clear about what I think now than I was --

[Laughter.]

DR. CROSSON: Well, next time, we'll have you go first.

DR. MILLER: Thank you, Cori.

MS. UCCELLO: I think this is a really rich discussion, and it's really made me think, so I think that's a good thing.

In terms of the first, this seems reasonable. I mean, I do -- I kind of have to comments on this. One is that, kind of what Kate said, well, this is designed to be budget neutral, assuming no changes in utilization, but assuming changes in utilization, we would hope that there would be some savings here.

But, to the extent that we're not actually even sure that there would be, this causes me some concern. I mean, it seems in theory that, yes, we should get savings, but I don't know. So trying to do something that's more explicitly, getting savings seems better.

Also, this is more a psychology thing. I think I'm comfortable with this 4 percent and the 980, but it's partly how you frame the choices. This is the middle-of-the-road choice, in a sense, between other choices. If we frame the range differently, would this still be where I end up? I don't know. What if the choices were all flat fee, no percentage, the 2.5 percent is the middle and then

the 4 percent as the other end? Well, would we then kind of migrate to 2, 2.5? It's just something to think about.

That goes back to thinking are providers going to be able to cover their expenses with this, is that going to be enough, and that factors into that. So maybe we still would end up at this four, but just thinking about how things are framed, it can affect kind of where you come down and where you're comfortable in when you think you're choosing the middle choice.

Regarding the 340B, can you put this in the transcript? [Waving hand.]

MS. NEUMAN: [Speaking off microphone.]

[Laughter.]

MS. UCCELLO: I'm hand-waving.

So I share these concerns about how do we best target extra funding to these kinds of providers, while at the same time making sure that Medicare is not cross-subsidizing things that it shouldn't.

So, again, this again seems like an appropriate middle-of-the-road approach. I like how both the beneficiaries and the program would benefit from this. I still think we need to kind of think through the broader

implications.

DR. CROSSON: Okay. I think we have exhausted our time. Perhaps the entire Commission -- so I'm going to sum up.

What? What?

DR. MILLER: Just before you do --

DR. CROSSON: Yeah.

DR. MILLER: -- can I just ask two other things? And, now, this is mostly for the three of you. So 340B was created when originally?

MR. WINTER: 1992.

DR. MILLER: Okay. And ASP+6 was created?

MS. NEUMAN: 2006.

DR. MILLER: And then November 5, 2015PPACA expanded things 2010.

So one thing about congressional intent, the original program was put in place before ASP+6 was in place, but then you might come back and say, "Yes, but in 2010, they expanded it, fully cognizant." But, in terms of intent, things happen in different times in different environments, and so I just wanted to kind of remind everybody how this -- the dominoes actually fell here.

And then I just want to also -- so the discounts that occur under 340B are for all -- I mean, implicitly, all payers, right?

MR. WINTER: Yes, they do. But Medicaid is a bit complicated because hospitals can choose whether or not to --

DR. MILLER: I'm sorry. I shouldn't have said all payers. I should think --

MR. WINTER: But commercial and Medicare, yes.

DR. MILLER: Commercial and Medicare. And so keep in mind that the revenue you're seeing here is not all of the revenue, but your immediate response, Jack, should be yes. But these are the hospitals that are likely to have less in terms of private pay, and that's a true statement too. But keep in mind, this is not all of the revenue that the hospital is pulling from 340B. There's also a private payer.

I apologize.

DR. CROSSON: So here's what I think I heard. With respect to the first portion of this, the ASP+6, I heard a lot of different opinions, but there were a lot of different reasons for hesitancy.

I heard a couple of "Let's go get 'em. Let's go get it," but I didn't hear a lot of that.

There were some suggestions about other ways to look at it, and so my suggestion on this one, because I have to predicate this, our intention is, again, to come back in March and to start looking hard at some recommendations.

In a category that's easy for me to say, I think we need to perhaps come back with some broader thinking on this piece because I don't see right now a consensus to do this, at least in the way we've suggested. We might be able to get there, but I don't know.

With respect to the supplier and dispensing, I didn't hear any arguments against it, so that one is in the bag, I think. Of course, when we get to the details, then it will be harder on the face of it.

With respect to 340B, I think what I heard is a general sense that we should be moving in this direction in some way, and my hope is this, that by the time we get to March, we will have had a broader -- perhaps not comprehensive, Jack -- but a broader discussion about payment to hospitals, including potentially payments to

different types of hospitals. And we may have a different sense of things that provide some comfort to moving in the direction that we've recommended by March.

And so I'm not going to suggest we overhaul that part at the moment, but that we consider revisiting this again in March when we've had a more comprehensive discussion about hospital and made recommendations, by the way, about hospital updates.

How does that sit with folks? Okay. All right.

Good. Well, thank you, Kim, Ariel, Dan. We will move on to the next topic.

[Pause.]

DR. CROSSON: I'm assuming the line at the bathroom is rather long, and we need to get going here.

[Laughter.]

DR. CROSSON: Okay, so we’re going to move on to the next presentation. This is, again, a continuation of work that the Commission has been doing for many years on the issue of support, including financial support, for primary care. The general concern here being that, for various reasons, and based on a lot of different evidence, the differential in payment between primary care and

specialty care -- in some specialties anyway -- is potentially having an adverse effect on the program and the beneficiaries.

We have had a policy which was enacted to provide a 10 percent add-on payment to primary care physicians. That legislation is expiring at the end of this year. So we're going to discuss renewing that, but renewing it in a different way, both in the way that the payment is constructed but also potentially the level of payment to primary care physicians.

So Julie and Kevin. Julie, are you going to start? Kevin is going to start. Thanks.

DR. HAYES: Good afternoon. The objective then of this session is to identify next steps that the Commission could take to further support primary care for Medicare beneficiaries.

We will begin the presentation with background on concerns about support for primary care and the Commission's recommendation on a per-beneficiary payment for primary care. To aid your discussion of next steps, we will then describe our preliminary investigation of two beneficiary-centered payment models.

The first model is full fee-for-service payment for all services furnished by primary care practitioners plus a monthly per-beneficiary payment.

The second model is one that could be called partial capitation plus. It would pay a monthly per-beneficiary payment, as in the first model, but it would also allocate a portion of the traditional fee-for-service payment to a capitated payment.

As you will see when Julie describes these models, complexity increases as payment moves further in the direction of payment that is beneficiary-centered.

The Commission, of course, has longstanding concerns about the fee schedule for physicians and other health professionals, particularly as it pertains to primary care. It undervalues primary care relative to specialty care. It creates disparities in compensation with physicians in some specialties receiving compensation more than double that of physicians in primary care specialties.

Here we see two examples of the disparities based on data from the Medical Group Management Association. In 2012, average annual compensation for physicians in family

medicine was $216,000 while the average for cardiology was $503,000. Such disparities can give medical students and incentive to choose careers in specialty care instead of primary care. Associated imbalances in physician supply present risks over the long run for beneficiary access to care.

And lastly, the fee schedule is not well designed to support care coordination. Let me expand on this last point, as it is one that is relevant to beneficiary-centered payment models.

The fee schedule is ill-suited to support care coordination because it is oriented toward payment for discrete services. For the most part, these services have a definite beginning and end. By contrast, primary care requires ongoing activities that are often not face-to-face with the patient. Examples include supervising and managing the practice's clinical team, reconciling medication prescribed by multiple providers, and developing and continually updating the patient's care plan. Such care is believed crucial to a more coordinated and efficient health care system.

In response to these concerns, the Commission

recommended in March of this year a per-beneficiary payment for primary care. It would replace the expiring primary care incentive payment program, a program that includes a 10 percent bonus on fee-for-service payments for eligible services and eligible practitioners.

The Commission's recommendation, while replacing the PCIP with a per-beneficiary payment, would retain the same definition of primary care services. That is, office visits, nursing facility visits, and home visits. And it would retain the same definition of primary care practitioners, physicians with a specialty designation of family medicine, general internal medicine, pediatric medicine or geriatric medicine plus nurse practitioners, clinical nurse specialists, and physician assistants.

Further, the per-beneficiary payment would be funded by reducing the fees for all other services.

The rationale for the recommendation was that additional payments for primary care should continue. However, the goal, in addition to rebalancing payments toward primary care, becomes one of moving from service based fee-for-service to beneficiary-centered payment, a form of payment more in line with care management.

Upon conclusion of work on this recommendation, several of you asked us to come back with more on the ways to implement a per-beneficiary payment. Toward that end, Julie will now offer some ideas by describing two payment models that would make payments for primary care more beneficiary centered.

DR. SOMERS: Thank you, Kevin.

To motivate your discussion about how to reform fee schedule payment for primary care, we present two models. The first model pays primary care providers full fee-for-service plus a monthly per-beneficiary payment for care management. The second model, called partial capitation plus, pays a monthly per-beneficiary payment as in model 1, but it also allocates a portion of the traditional fee-for-service payment to a capitated payment.

The goals of both models are to rebalance the fee schedule and to give primary care providers more flexibility to optimally structure their practice and choose the activities that promote efficient, high quality care.

For example, more flexible payment could support team-based care, telehealth services, or a pharmacist on

staff to assist with medication management. However, there are a number of issues with these models that would make implementation a challenge. We will highlight those issues as we proceed.

The two models build on the Commission's per-beneficiary payment recommendation. The Commission recommended funding the per-beneficiary payment within the fee schedule. This graph explains the approach. The white rectangle on the top represents of the fee schedule spending on primary care visits provide by primary care providers. The per-beneficiary payment would be paid to those primary care providers providing primary care visits.

Next, the light gray rectangle in the middle of the graph represents the 15 percent of the fee schedule spending on primary care visits provided by specialists. Their payment remains unchanged.

The dark gray rectangle at the bottom represents the 75 percent of fee schedule spending on all services other than primary care visits. So this would be things like procedures, imaging, and tests. The Commission recommended funding the per-beneficiary payment with a reduction in payment for these other services.

So as we move to the next slide, please keep in mind the sets of services in the top 10 percent and the bottom 75 percent portions of the chart.

The first model is a straightforward extension of the Commission's per-beneficiary payment recommendation. In that recommendation, as indicated in the first highlighted row, the per-beneficiary payment rate would be $2.60 cents per month, an amount chosen to replace the expiring primary care bonus.

The Commission recommended funding that payment with a 1.4 percent reduction in payment for all services other than primary care visits. The share of fee schedule spending on primary care provided by primary care providers would increase by a small amount, from 10 percent currently to 11 percent, and the share of fee schedule spending on all other services would decrease by a small amount from 75 percent currently to 74 percent.

Payments to primary care providers would increase by about $3,800 on average, or about a 7 percent increase. But of course, the per-beneficiary payment rate could be increased. The increased payment rates shown in the table are multiples of $2.60.

So take, for example, a per-beneficiary payment amount of $10.40 per month. The share of fee scheduling spending on primary care provided by primary care providers would increase from 10 percent to 14 percent and payments to primary care providers would increase by more than $15,000 on average, almost a 30 percent increase. However, it would require a 5.6 percent reduction in payment for all other services.

The benefits of model 1 are that it would increase payments to all primary care providers, rebalance the fee schedule by increasing spending on primary care, and add payment on a per-beneficiary basis, giving providers more flexibility to optimally structure their practice and choose the activities that promote efficient, high quality care.

However, model 1 is still primarily a service-centric fee-for-service model and so would incentivize the overprovision of billable services and the underprovision of non-billable services.

Finally, across the board payment reductions would apply to over-valued services, but they would also apply to correctly-valued, and under-valued services.

Now moving on to model 2, partial capitation plus. Under model 2, payment for primary care providers would have three components. Two of the components would come from splitting the traditional fee-for-service payment into a per service payment for primary care visits and a partial capitation payment per-beneficiary. The third component is an add-on per-beneficiary payment, the same as in model 1.

The objective of model 2 is to move a proportion of the payment for primary care visits from fee-for-service to a partially capitated payment to give providers even more flexibility compared to model 1 to optimally structure their practice.

The benefits of model 2 are that it would rebalance the fee schedule by increasing spending on primary care and give providers an even greater share of payment on a per-beneficiary basis, increasing provider flexibility to determine how best to provide quality care. However, like model 1, model 2 has the problem that across-the-board payment reductions would apply to over-valued services, correctly-valued services, and under-valued services alike.

In addition, model 2 has a special issue. It redistributes payments among primary care providers. We'll discuss this point in a moment.

But first, let's compare model 1 with an example of model 2 that allocates 60 percent of traditional fee-for-service to a per service payment and 40 percent to a partial capitation payment.

On this slide, we have the same table that we looked at before, just with two additional columns at the end. Let me draw your attention to the second of the two highlighted rows, just as before, an add-on per-beneficiary payment rate of $10.40 per month would require a 5.6 percent reduction in payment for all other services. And in both models, payment to primary care providers would increase by more than $15,000, on average, or almost a 30 percent increase.

The difference between the two models is highlighted in the last two columns. Model 2 almost doubles the share of payment paid on a per-beneficiary basis at 43 percent compared to 22 percent in model 1. Why the difference? It's because both model 1 and model 2 have the add-on per-beneficiary payment but model 2 also has a

partial capitation payment allocated from fee-for-service.

Now let's examine model 2's special issue of redistributing payments among primary care providers. As an illustration, consider our model 2 example that allocates 60 percent of traditional fee-for-service to a per service payment and 40 percent to a partial capitation payment. When provider A, with 200 beneficiaries, moves from traditional fee-for-service to model 2, she trades 40 percent of her average fee-for-service payment multiplied by her 200 beneficiaries for 40 percent of the system-wide average fee-for-service payment multiplied by her 200 beneficiaries.

So if her average fee-for-service payment is greater than the system-wide average, she earns less under model 2 than under traditional fee-for-service.

Of course, average fee-for-service payment is a function of payments per visits and visits per beneficiary. So in general, model 2 redistributes payments from providers with higher payments per visit to providers with lower payments per visit and from providers with more visits per beneficiary to providers with fewer visits per beneficiary.

There are at least three options to mitigate model 2's redistributive effects. First, a higher per service payment rate could be set. So for instance, 90 percent of the traditional fee-for-service could be allocated to the per service payment instead of the 60 percent used in our example.

Second, payments under model 2 could be risk-adjusted. High intensity providers may furnish more and higher level office visits than the average provider in the system because their patients are sicker. Risk adjusting payment for health status would increase payments to those providers.

Finally, the add-on per-beneficiary payment rate could be increased. Enough additional money could be added to primary care to ensure that all primary care providers earn more under model 2 than under traditional fee-for-service.

Now let's move on to consider a few design features that apply to both models. First up is beneficiary cost-sharing. For the per-beneficiary payment, the Commission recommended that beneficiaries should not pay cost-sharing. The Commission was concerned that

beneficiaries may question cost-sharing in the absence of a face-to-face visit.

Consistent with the Commission's recommendation, in these examples we have assumed no beneficiary cost-sharing on the add-on per-beneficiary payment in either model. And we've assumed that per-beneficiary cost-sharing remains the same on the fee-for-service payment even when a portion is allocated to a partial capitation payment, as it is under model 2.

Next up are practice requirements and performance measures. For the per-beneficiary payment, the Commission did not recommend practice requirements out concern that an amount of $2.60 per month would be too small and also out of concern about the lack of evidence to support the effectiveness of practice requirements.

The Commission also did not recommend performance measures. It would be difficult to measure performance on controlling costs and improving quality for providers in practices with small Medicare patient panels since random variation in the health of patients could have strong impacts on costs and quality measures.

One possible solution would be to focus on

persistent statistical outliers. For example, CMS could identify providers whose performance is consistently in the best and worst performing decile of all providers and adjust payment up or down accordingly.

The last design feature to consider is beneficiary attribution. It is here that the Commission may choose to reopen its discussion. In the past, the Commission has supported prospective attribution in the context of its work on ACOs and for the per-beneficiary payment recommendation. In prospective attribution, CMS would attribute beneficiaries to primary care providers based on the plurality of primary care services received, simplifying the administrative process for CMS, providers, and beneficiaries.

However, as the share of payment paid on a per beneficiary basis increases, getting the attribution right may become more important. If beneficiaries switch providers, providers would be paid for beneficiaries no longer under their care. Additionally, under model 2, if a beneficiary receives primary care visits from additional providers, Medicare would pay more for visits in the aggregate.

As an alternative, beneficiaries could designate their primary care providers through written consent. Beneficiary designation could encourage a dialogue between the beneficiary and the provider about responsibilities for providing coordinated, patient-centered primary care and hold the provider accountable to the beneficiary. However, beneficiaries may feel pressured to sign consent forms in their provider's presence.

And finally, beneficiaries would need to be allowed to change their designations. But how frequently should this be allowed to occur? Frequent changes could become administratively unwieldy and could hamper the policy goal of encouraging coordinated care.

That concludes our presentation. For the Commission's discussion, you may want to address whether these are the right goals to balance the fee schedule by increasing spending on primary care and to increase the share of payment on a per beneficiary basis in order to increase provider flexibility.

You may wish to discuss your preferences for model 1 or model 2.

Two questions to guide those preferences are how

much should be added to primary care? And what share of payment should be paid on a per beneficiary basis?

You could discuss any of the design issues, but we highlight two here that we think require the most attention. These are model 2's issue of redistribution and model 1 and two's issue of attribution.

With that, we thank you and look forward to your discussion.

DR. CROSSON: Okay, Julie, Kevin, thanks very much.

We're going to move into clarifying questions in a second. I'll start with one, and it's on page 18, the issue of written consent. So I'm trying to remember exactly, but it seems to me we've been down this path before with respect to ACOs, and that's a while ago.

It seems to me that at the time when we were looking at options there we were talking about something that we called attestation, or acknowledgment, in other words, the acknowledgment in this case potentially by the provider or physician or other qualified health professional -- thank you -- as well as by the patient or by the beneficiary that a relationship existed, which is a

little different than consent.

So when we're saying "consent," do we mean something more than that idea? Does it, in fact, lock the patient or the beneficiary in, in some way, or is that not the intent?

DR. SOMERS: So that's all up for discussion of what it means. When I think of written consent, I think of the primary care provider telling the beneficiary: These are the services I can offer you. I would need your written consent to offer them and to be reimbursed for them through Medicare.

And in terms of -- and then it's -- and to tell the beneficiary, perhaps: You can't go see another primary care provider except for me while we are under this agreement.

And then it would be a question. I think you'd want the beneficiary to be able to walk, to go somewhere else, and sign a new written consent in order to hold the provider accountable. But you don't want that to happen so much, or to allow it to happen so much, that it just becomes a visit-to-visit thing there's a new designation.

DR. CROSSON: Right. Okay. So, yeah, Mark.

DR. MILLER: I'm not sure I would read too much into the choice of words. We were trying to put back on the table: Do you want some agreement, something written, between the provider and the beneficiary, and if so, what does it mean? Is it merely we acknowledge this, or is it some kind of a lock-in?

DR. CROSSON: Right, right. So there's some fungibility there because I think you could get some of the benefits you have here, for example, encouraging beneficiary dialogue, practitioner, sorry, practitioner dialogue, but without the negative one, which is the beneficiary feeling pressured in some way because the pressure presumably would come from some sort of loss of power, which doesn't necessarily have to exist. Matter of fact, you described the fact you don't want it to exist because the beneficiary should be able to move.

So simply acknowledging, or attesting, to the fact that a relationship exists... anyway.

DR. MILLER: I mean, I think when we had these conversations in the ACO world I think the reason that Julie is bringing that concern up is so you go to a provider, and the provider says: Look, I want to be your

primary care person, and I can get this payment in order for me to provide these coordinating services, but I need you to read this, sign this piece of paper, or acknowledge something here.

And the conversation was -- what's the structure of that conversation? Who sits there and says to the provider in that instance, well, not you?

And then let's say you go to another office, and the person approaches you and says: I would like to be your primary care person. I want you to sign this.

And so I think that was the concern that -- one of the concerns that Julie was raising, that if you don't end up -- well, I'll stop.

DR. CROSSON: But I think what you're saying is then that would require somebody to withdraw the first one.

DR. MILLER: Right.

DR. CROSSON: Right.

DR. MILLER: And then Julie's point was if that happens every 30 seconds, maybe that's a little too much drama. But you know, if that happens every few days or every month or something, then exactly who's coordinating what, and how does CMS keep up with who's actually getting

the per capita.

DR. CROSSON: Right. And what's the process for withdrawing one?

Anyway, okay. Thank you. That was my question. And if I violated my own standards, I stand accused.

Qualifying -- clarifying --

DR. MILLER: Distorting.

[Laughter]

DR. CHRISTIANSON: [Presiding.] So there's probably a lot. But why don't we just start with Alice? Is that okay, Jack? Can we just go around and make sure everybody --

DR. COOMBS: So can you go to page 20 in the handout? I just had a little difficulty just kind of transcending.

You put the pros and cons on Model 2. You posted that up there on the slide. But in the handout, can you tell me how would a provider deal with uncertainty with that Model 2? Is there built into the system some way to address uncertainty?

DR. SOMERS: So, Alice, do you mean if they have a different number of visits per beneficiary?

DR. COOMBS: Different number of visits per beneficiary, yeah.

DR. SOMERS: And different payment. I'll put the -- oh, is this still clarifying?

So there is this redistribution effect if you take a percentage of their fee-for-service payment that's now based on services and you put that all into a pot and you redistribute it based on beneficiaries kind of at a systemwide average. It's not really uncertainty. There just will be winners or losers --

DR. COOMBS: Usually losers.

DR. SOMERS: -- depending upon how you fall around the average.

But then we have ways that you could mitigate that, and one is the -- I'd really like to emphasize that the tables on page 20 in your handout --

DR. COOMBS: Right.

DR. SOMERS: -- have not yet added any money to primary care. So they don't have that add-on per-beneficiary payment of the $10.40 per month.

So that would go a long way at making sure that everyone earns more under Model 2 than under traditional

fee-for-service.

DR. MILLER: Every primary care.

DR. SOMERS: For primary care. So these tables in your handout were just trying to show the clean effects of what happens when your visits per beneficiary are different from the average, or when your payments per visit differ from the average, before we've added on payment.

DR. BAICKER: Quick question. You mentioned prospective attribution and written consent. Is there a retrospective true-up that's on the table, or is that logistically not feasible or not a thing we could do to reconcile?

DR. MILLER: Apparently not. We hadn't been thinking about things that way, which is not to say that we couldn't, and if you want to put it on the table, you can.

I think we've been trying to think of what's administratively, both for the provider and bene and CMS, on the size of the transaction, the easiest to kind of work through, but we could talk about it.

DR. HOADLEY: So, following on Alice's question, I mean, the table in the handout in the mailout on page 20 was obviously done as a hypothetical. Do you have a sense

of how much spread there is among providers on these two dimensions of visits per beneficiary and sort of payment per visit?

I mean, it makes a difference if, you know, they're very clustered around the mean versus there's a whole bunch of spread. And so, I mean, you may not have that right now, but that would be something if we're trying to think through this. How big a problem are we trying to fix?

DR. SOMERS: Yeah, I think there is a lot of clustering around three visits per beneficiary. And I can't quite remember on payments per visit. So I'll have to get back to you on that one.

DR. HOADLEY: But those would be the sort of dimensions that -- you know, if it's small, if it's well-clustered, then we don't necessarily have something we need to fix.

On slide 12, this is really more just Model 1 versus Model 2. I think I'm understanding this correctly, that it's only the add-on that would be funded out of the 70 percent on that previous graph.

DR. SOMERS: That's right.

DR. HOADLEY: And that all of the sort of -- the thing on the right-hand side of that table is funded out of the cluster of the primary care providers.

DR. SOMERS: Well, the right-hand side does actually include both the add-on-

DR. HOADLEY: Okay.

DR. SOMERS: -- for beneficiary payment as well as the, in this example, 40 percent of the fee-for-service payment that you're paying as a capitated amount. So it includes the total.

DR. HOADLEY: So my question is really the 40 percent is all funded out of the primary care universe.

DR. SOMERS: Yeah.

DR. MILLER: Yes. And if you want to flip to 10 for a half a second, if you think of 10 as the 3 pieces, it's only the add-on piece that's funded by taking from the other part of the fee schedule.

And then number 2 is from primary care, but it's just put into a per-person.

DR. HOADLEY: Got it.

DR. MILLER: So your instincts are on point.

DR. HOADLEY: Okay. And then my last one is I

think I understood on the cost-sharing that the partial capitation payment would still have cost-sharing related to it.

DR. SOMERS: That's right. So the same cost-sharing under traditional fee-for-service would apply.

DR. HOADLEY: And have you thought at all about sort of the mechanics of that because does that mean the beneficiary has to write a monthly check, or I mean, what would that translate into in the real world?

DR. MILLER: The way I think we were thinking about this is the beneficiary pays their normal copayment when they have a visit.

DR. HOADLEY: And so, collectively, across all the visits it would come out, but the beneficiary wouldn't be paying it relative to the -- okay.

DR. MILLER: And, in theory, even though 60 -- I mean, in this hypothetical example, 60 percent of the fee schedule rate is paid at that time; in parentheses, 40 percent was paid on a per-capita basis earlier in the year, let's say.

The beneficiary's perception should be: It costs $100 for this office visit. I paid 20 like I always did,

and I'm not paying copayment on the add-on part.

So that's the way I think we were envisioning things, at least as a starting point, unless you have a different idea.

DR. HOADLEY: No. I think that sounds better than what I was worried about, that it was complicated, although you'd have to think about things like then on their EOB, if it said, well, the doctor really only got whatever the numbers are, $60, and they paid 20, then it's going to look like they're paying more than 20.

DR. MILLER: Exactly. And I said, you know, because it was real easy for me to say, the general perception should be its 100 bucks, but if they're carefully looking at their EOB they are going to notice that, hey, it was 60 bucks; what's up with that?

DR. HOADLEY: What's up, yeah. So just details, at some point, we can think about.

DR. CROSSON: [Presiding.] Clarifying questions? Mary. Which way are we going? Sorry. Yeah, Mary.

DR. NAYLOR: [Off microphone.]

DR. CROSSON: Which way are we going? Sorry.

DR. CHRISTIANSON: We're going to the left. So,

Mary.

DR. CROSSON: Yeah, Mary.

DR. NAYLOR: So I just want to clarify that when you're talking about the additional 10.60 per beneficiary, 15,000 plus per year, that you know, this notion in Model 2, the redistribution, everybody's boat has risen here. Is that right?

Can you simulate what impact that would have -- the redistribution? I think it's building a little bit on this, with existing information about numbers of visits and so on, although all that, I suspect, would change. But can you simulate what the impact would be across a typical practice in redistributing?

DR. SOMERS: Yes, we can give a very rough idea of what that would be and maybe what the add-on would need to be to kind of make everyone whole, or make everyone earn more.

DR. NAYLOR: I'm just saying that there's this notion that there are winners and losers, but I'm not exactly sure that that's going to be the -- I mean.

DR. SOMERS: Right. If you're just talking about the add-on?

DR. NAYLOR: Yes.

DR. SOMERS: That makes everyone earn more.

DR. NAYLOR: Yes.

DR. SOMERS: That makes everyone a winner.

And it's just when you change the way you're paying and divide the fee-for-service payment up into a capitated portion, and the per-service portion is what creates the winners and losers. And that's just surrounding the fee-for-service payment as it is, not with the add-on.

So you're right, that everyone can earn more-

DR. NAYLOR: Right.

DR. SOMERS: -- if the add-on is big enough.

DR. NAYLOR: So the other thing I'm wondering is, in terms of the evidence base to support one or the other of these models, there's a fair amount of work around what happens when you add care management to fee-for-service versus when you get engaged in real practice transformation. And I'm wondering if that might help us in thinking about the best choice here. There is huge investment from CMMI and others in practice transformation.

And the last thing, on performance incentives,

I'm wondering with $2.60, we didn't go there. But I think that it would be helpful to think about what we have learned with NCQA's and other's assessment of even small practice relative to performance, to think about what we might be able to glean if we move toward a more performance-based, patient/beneficiary-centered model.

[Off microphone] Did I go into the next [inaudible]?

DR. MILLER: No. I mean, the last question is tipping in the sense that it sounds like you might want to go into performance-based, but that's not what I want to deal with.

You very quickly said, $2.60, but we didn't go there.

DR. NAYLOR: So we didn't engage in defining practice requirements, and we didn't-

DR. MILLER: Now I'm with you.

DR. NAYLOR: Yeah.

DR. MILLER: No problem. I understand what you said.

DR. CROSSON: David.

DR. NERENZ: Just either 8 or 12, whichever one

you get to easiest because it's the same table, just the two models. The third column, the reduction. Those figures are made on assuming basically a no-change model in the sense of quality utilization. So, for example, if you change primary care payment, you're assuming no change in number of ED visits, no change in unnecessary tests, no change in avoidable hospitalizations.

So it's just purely about the dollars. Every dollar you put into primary care you've got to take out of somewaplace else. That's the --

DR. SOMERS: That's right. It's a static --

DR. NERENZ: Yeah. Okay.

DR. SOMERS: -- 2014 look, yeah.

DR. CROSSON: Bill.

MR. GRADISON: Two questions. Congress recently acted in a sense on this subject. They didn't move any money around, but they did provide modest increases, about a half a percent a year for a while. Then, in 2019, it moves into a choice for physicians between going into the alternative payment methods, the APMs, or into the MIPs, the Medicare Incentive Payment system.

Question. And you may want to give a little

thought to it and come back to it. Does that choice that has to be made tip one way or the other to benefit primary care physicians versus people who are not doing primary care?

I'd just ask you to mull that one over because there may be some things built in here under the surface that may influence this one way or the other. So that's the question. I'm not expecting an immediate answer.

A more specific question is how would this recommendation, either one of these recommendations, play out with regard to new physicians that are just building a practice and have a relatively small panel versus those who have a larger establishment?

I understand one would make more money, but I mean in terms of the payment that they would receive per patient as they sign up new patients. Is there anything in this that would tend to disadvantage somebody who's trying to build up? There may be a few out there who are still trying to do this that aren't working for hospitals, maybe more now since Monday, but I just would wonder if you have given any thought to how that would play out.

And if you want to come back on it, it's fine.

DR. SOMERS: Well, the first thing that comes to mind is that, you know, some think of this care management or this additional money to support some care manager, or often it's a pharmacist on staff. And so in terms of a physician just -- or some provider just -- starting out, you would need enough money up front to pay that salary. So there is probably an amount of Medicare beneficiaries that you need in your panel, to be collecting this money, to be able to pay that care manager or that pharmacist on staff. So there would be a threshold there.

DR. MILLER: But there's nothing about this policy that particularly advantages or disadvantages a new or established physician more than, you know, current.

DR. SOMERS: Yes.

DR. MILLER: Right. That's right.

DR. SOMERS: I'm speaking generally to the issue of giving money for care management.

DR. CROSSON: But, Bill, with respect to the MACRA, one could honestly conclude that Congress was at least considering your point; that is, it might be easier for primary care physicians to qualify for alternative payment models. And the reason is that, as you may

remember, they established a separate commission. I've forgotten the name exactly of it, but it was on physician payment something, which was specifically designed to look at the potential for alternative payment mechanisms for specialists.

And at least in reading it through, it looked to me like that was based on the concern that maybe you had, which was that in the end, as this plays out, the alternative payment mechanisms may be either more attractive or easier to manage for primary care doctors.

MR. GRADISON: On the others, I agree with that, but the thing that's kind of bothered me about some of those proposals is that if I were a primary care physician trying to look good from a qualitative point of view, if there was ever a close case, I'd send them to a specialist --

DR. CROSSON: Right.

MR. GRADISON: -- which runs up the cost, but it may provide better numbers for the primary care physician in terms of outcomes.

DR. MILLER: I think on the MIP side of things, I think what Jay was referring to was APM.

MR. GRADISON: APM side.

DR. CROSSON: And, again, that is an area where I think we have yet to see some of the salient details.

Where are we? Kathy.

MS. BUTO: Julie, I wondered if -- I don't know that we've talked that much about it, but the risk adjustment payment that you mentioned as a way to mitigate some of the redistribution, were you thinking of that as something that would be based on the individual patient's diagnosis as opposed to the pattern of practice of the physician? Because just because they did more visits or higher-level visits, you wouldn't necessarily want to --

DR. SOMERS: No.

MS. BUTO: -- risk-adjust for that, right?

DR. SOMERS: Right, right. I was thinking something that applied to the patient, like their individual risk score.

MS. BUTO: And I guess what surprised me is I assumed we'd want to have something like that because otherwise, really, physicians who treated more difficult, more chronically ill patients, et cetera, would be so disadvantaged in a situation like this. I guess I'm

thinking this would have to be built in, in some way, and I don't know if you were thinking of it that way.

DR. MILLER: So I think what we were thinking is it might drive you off of two altogether if you started to think about the complexity there and say, well, this is a level of complexity that you -- "you" meaning the Commissioners -- weren't contemplating. That might drive you back to model 1 where this isn't an issue. That's one thought.

A second thought is -- and some of this drives off of what Jack said -- if the clustering is not all that much variation, you could decide, well, maybe not so much, or just to make this as complex as hell, you could take not 40 percent but take 20 percent or 10 percent if you felt that there were ways to mitigate this.

And so I think the way we were thinking about it is we weren't immediately jumping to risk adjustment. We were thinking there might be other ways you could mitigate or risk-adjust, or you might even walk away from the model.

MS. BUTO: Just to add one other element -- this is my second question.

DR. SOMERS: Oh, could I --

MS. BUTO: Go ahead, sure.

DR. SOMERS: -- just tag onto Mark's?

There was one other thought that we put in your mailing materials on risk adjustment, so not to totally sink model 2, but that you're still saying -- you're still paying, in our example, 60 percent per service, the 60 percent of fee-for-service per service. So to the extent that the doctor has a lot of visits per beneficiary or has a lot of level 5 office visits instead of level 1 office visits, they're still going to receive more money for those visits.

MS. BUTO: In addition to the capitated payments?

DR. SOMERS: In addition to the capitated payments.

MS. BUTO: Okay.

DR. SOMERS: And the capitated payment won't change unless we do some sort of risk adjustment.

MS. BUTO: Yeah. No, that just seems to me to weaken the capitated payment part of this --

DR. SOMERS: Okay.

MS. BUTO: -- if we're going to do that kind of a -- that's inherently a risk adjustor, in some ways, I

guess, except it's more based on the level of care than it is based on the patient's condition, right?

DR. SOMERS: Right.

MS. BUTO: My second question is really about what's in the capitated payment, and it sounds like it may be just visits, not tests or screening or any of that other stuff, unless it's included in the visit and not paid for separately.

DR. SOMERS: Right now, the example is just visits, but everything is open for discussion.

MS. BUTO: Yeah. Because, I mean, if we think beyond just sort of the idea of capitation, at least in my mind, something we could think about, I guess, for Round 2 is, if we're really trying to think about practice, what should be in that capitated payment. What else would we include in it?

DR. SOMERS: Well, under the fee schedule, I think, on average, these primary care visits account for 70 percent of the primary care providers' billings, and if you expand that, we have a very narrow definition of primary care visits, where it's just the office visit, nursing facility visits, and home visits. But, if you expand it to

all E&M and include the inpatient hospital visits that they make and ER visits, then it's over 90 percent of billings under the fee schedule are for E&M visits. But that doesn't include tests or DME. So there are some other things that we could look at.

DR. CROSSON: You know, Kathy, this is anecdotal, but having been in charge of a primary care department personally early in my career, in a situation where the physicians were paid on salary, I can tell you that there was very broad variation in terms of the risk or the disease burden that was being managed by different physicians, depending upon both their interests but also their openness to patients with complex and chronic conditions, quite frankly.

I wouldn't know how to quantitate that, but it was very obvious, and all the physicians in the department knew well which ones were carrying the heaviest burden in terms of complexity.

Craig? Oh, I'm sorry. Did you have a --

DR. SAMITT: I have a clarifying questions.

DR. CROSSON: Yeah, yeah.

DR. SAMITT: Just quickly, on slide 10, when we

think about the distinction between the partial capitation payment per beneficiary and the add-on, are we thinking the methodology would be equal? One is a redistribution of the prior fee-for-service payment; one is incremental. But they're both per-beneficiary payments.

DR. SOMERS: They're both per-beneficiary payments, and when you look at the table here --

DR. SAMITT: You've added them together.

DR. SOMERS: -- I put them together to say it just increases your -- model 2 increases the share of your payment paid on a per-beneficiary basis because you get both fee and per-beneficiary payment, where you're increasing money to primary care --

DR. SAMITT: Yep.

DR. SOMERS: -- and you get the part that you're capitating. Yeah.

DR. CROSSON: Rita.

DR. REDBERG: So it's implied in this chapter that you have one primary care provider, but is that actually stipulated, or could you have more than one?

DR. SOMERS: I think you have to have one so that --

DR. MILLER: Or at least only one that gets --

DR. SOMERS: One at a time, right.

DR. MILLER: That gets the per.

DR. SOMERS: Only one that gets the capitated payment and the add-on per-beneficiary payment. You don't want to be paying twice.

And for care coordination, you ideally would like one primary care provider for your beneficiary. Now, that might change over time.

DR. REDBERG: Really, you have data -- it's my impression that people do have more than one primary -- what they call primary care provider, certainly more than one cardiologist.

DR. SOMERS: So we looked at this a little bit last year through the discussions of the per-beneficiary payment recommendation, and we have a pretty tightly defined group of primary care providers that we're dealing with here. There are specific specialties, and 60 percent of their billings have to be for these primary care visits.

So, for this group, about 69 percent of beneficiaries only have one, have the same primary care provider for a year, and we looked over 2 years, and that

drops to 60 percent of beneficiaries have the same provider over 2 years. So there's a bit of noise there, but, hopefully, the policy -- well, one of the goals I think of the policy would be to encourage a tighter relationship between the beneficiary and a primary care provider, and increase the percentage of beneficiaries who have one provider over multiple years.

DR. CROSSON: I'm sorry. I was just going to say -- I think you understand this, but, as I understand it, some patients, let's say, who have a specific chronic disease may in fact use a medical subspecialist, for example, as their primary care provider. Those individuals in this context are not included; is that right?

DR. SOMERS: That's right. The beneficiaries have to be seeing one of these primary care providers who are under the old Primary Care Incentive Payment program's definition of certain specialties and at least 60 percent of their billings are for primary care visits. Right.

DR. REDBERG: My other clarifying question, how many -- what percentage of Medicare provider physicians are identified as primary care, and how many are identified as specialists?

DR. SOMERS: Let's see. There are 183,000 providers in 2014 that were eligible for this primary care bonus payment, so that were of the specialties, and that's the group that we're dealing with here.

I don't remember. I can --

DR. HAYES: And we have about 500,000 physicians who are billing Medicare, so that works out to be roughly two-fifths or 40 percent that are in those specialties.

Now, it doesn't mean that they've crossed the threshold and become eligible for the PCIP, but those are the specialties, anyway.

DR. SOMERS: Well, no, the 183,000 are the ones eligible.

DR. HAYES: Oh, they are, yeah.

DR. MILLER: But the 183, it's not just physicians.

DR. SOMERS: That's right.

DR. MILLER: So the denominator shouldn't be 500,000. it should be more like, what, 7- or 800,000, and the number would be about 24 percent?

DR. HOADLEY: I wouldn't go as high as that or 800,000 because --

DR. MILLER: Well, what would you give me, Kevin? What would you give me?

[Laughter.]

DR. MILLER: How high would you go?

But, either way, it's higher than --

DR. REDBERG: Of the 183,000 are physicians?

DR. MILLER: No, no. The 183, just to clarify, is not just physicians.

DR. REDBERG: But how many are physicians? Do we know?

DR. MILLER: Oh, that, I don't know.

But, as a percentage of this, I would think that the denominator would get closer to 700,000 or thereabouts, and you would be more in the 25-35 range.

DR. SOMERS: We can get into that. We can get some more specifics on that.

DR. REDBERG: Thank you.

MS. THOMPSON: So I'm going to come out of the weeds, Julie. I love this discussion.

But, if we go back to what's the problem we're trying to solve, we clearly do not have enough primary care physicians. We're not incenting young medical students to

choose primary care as a residency, and access is decreasing. Do we know anything about what will it take in terms of the number to make a medical student look at primary care as opposed to a specialty?

I mean, directionally, this is all correct. It's correct around improving coordination of care, but are we moving quickly enough to address the access issues that we're facing?

DR. HAYES: We don't know what that threshold is. The Commission's view has been that we want to move in the direction of correcting imbalances in the fee schedule. The position has been that while access to care in general is good for Medicare beneficiaries, there is, over the long run, a risk for access to primary care, and so the goal is to sort of tip that balance and try to head off any long-run problems that might develop. But what the precise cut point is is hard to know.

DR. CROSSON: But it's more than a little.

Jon?

DR. CHRISTIANSON: Now, could we go to slide 13?

So, in model 2, you used as your example or your -- for instance, on higher payments for visits, more visits

coded level 4, level 5. Would higher payments for a visit also be visits provided by -- all else equal, provided by hospital-owned primary care practices?

DR. SOMERS: No. This is -- let's see. This is just --

DR. CHRISTIANSON: Aren't they allowed to bill at a higher level?

DR. SOMERS: They are. This is just the physician component.

DR. MILLER: This is on the fee schedule side, though.

DR. SOMERS: So it would actually go the other way. When you're looking at the payment per visit and the fee schedule if you're in a non-facility, you have those non-facility practice expenses embedded in there, and you have a higher payment rate per visit than if you're at a facility where there's a different check cut.

DR. CHRISTIANSON: So model 2, conceivably, transfers more income to hospital-based practices? I don't understand what you said. I thought you just said it went the other way, so --

DR. MILLER: So all right. I would answer this

question two ways. One, I would say to the extent that we're looking at the effects here, we're looking at the effects on visits that are given by providers and paid out of the fee schedule, and so, in a sense, all we're looking at, Jon.

But I do think you have a potential point, but let me see if I'm getting to it.

[Laughter.]

DR. MILLER: We're looking for it -- we're looking at it on the fee schedule side of things, and so to the extent that something gets bought and moved and billed through OPD, it wouldn't be in this analysis.

DR. CHRISTIANSON: Okay.

DR. MILLER: However, your point could be -- and then I'll just let it go back to you -- but if somebody comes along and purchases a practice, does this visit get reimbursed at the higher rate when that happens, and I think the answer to that is yes.

DR. SOMERS: Well --

DR. CHRISTIANSON: Do you agree with that? I feel like I'm mediating.

DR. MILLER: Why wouldn't it?

DR. SOMERS: So we can work on that issue. This is just looking at the physician fee schedule. So if a beneficiary goes to an outpatient, a hospital outpatient department and has an E&M visit, that's going to be --

DR. MILLER: But they would be still going to their physician's office.

DR. SOMERS: They'd be still going to their physician's office, so the price per visit under the fee schedule, because it doesn't have that facility payment to the outpatient in the fee schedule -- it's somewhere else in the Medicare payment system -- the price per visit in that outpatient facility under the fee schedule is less than what it would be if the physician was in his office.

DR. CHRISTIANSON: Maybe this is just something to take a look at.

DR. SOMERS: But this is -- yeah. So this would be a detail that would need to be --

DR. CHRISTIANSON: Yeah, I'd be interested.

The other thing I want to do is just commend you guys on the careful use of words in this statement of goals here. I mean, you did talk about changing the fee schedule. You did talk about paying for physician visits

as opposed to paying physicians more, because, obviously, we're in a world where more and more physicians are salaried employees of -- primary care physicians of organizations, so the organizations determine what physicians get paid. And the dollars that come for higher payment for services may or may not go into care coordination, may or may not be passed on, to some degree, to physician salaries.

So I think the way you've very carefully handled that I think underscores it when we think about behavioral responses to this. More and more, we need to think about organizational behavioral responses and not individual A is going to get more money for delivering primary care, and I think you set that up very nicely in your chapter in how carefully you sort of framed everything.

DR. SOMERS: Thank you.

DR. CROSSON: Okay. So, for this one, I don't have a straw-person, and, boy, do I wish I did.

[Laughter.]

DR. CROSSON: We are running a little bit late. I'm betting that our last session may take a little less than an hour and a half. We'll see.

So I'm going to suggest we do this, that we try to take on -- and I'm looking for a rapid fire "yeah, yeah, yeah," "no, no, no" stuff here, that we try to take on the issue of do people like model 1 or do people like model 2 better, right?

Then we take on the issue of the -- where we want to land on that ladder of payments and therefore reductions in payment to other specialties, and depending upon where we are then -- for example, if we're at model 2 and we're moving up the ladder, then I think we need some preliminary discussion about some of these other issues, including attestation, potentially risk adjustment, maybe we can defer practice requirements and performance measures for later. But that's sort of what I'm thinking is the logic chain here, okay?

So let's take them in discrete pieces. What's the sense of people in terms of model 1 or model 2? I like model 1 or I like model 2, and why or why not?

Mary?

DR. NAYLOR: I like model 2, although there's much to learn. But, anyway, so let me just give you some thoughts about why I think model 2 has advantages of

helping us get to the culture of care that we are seeking for Medicare beneficiaries. It places a focus on the practice versus the individual. It really promotes the kind of -- I mean, I think relative to model 1 -- promotes the kind of teamwork. It helps us to begin to think and move away from visits to contacts and the kind of thinking about using telehealth. I mean engaging the full repertoire of opportunities. It progresses our speed, I think, by taking this on, as complex as it is, to moving toward a more value-based model of care, getting us further along in capitation as the opportunity.

I think we really can add to some of the ways in which you have been thinking about it by placing attention on performance, and the whole notion of value and measuring practices relative to -- the value to the beneficiary. And that is not practice requirements. I think we should stay far away from that, but relative to how people's health is progressing, how their experience with care is, their healthy days at home, all the things -- and use of resources.

I do want to highlight that when you look at 183,000, even if you were to look at it, you wouldn't

really know what the denominator is. I mean meaning you won't know how many are physicians are nurse practitioners. Medicare's own work is suggesting the growing role of nurse practitioners and PA in the delivery of primary care.

And I think since many of these are still being billed incident 2, as we've gone through, we don't really know who's delivering these services. But we do know from the survey that we are increasingly relying on a very different workforce and a team-based model of care, and so I think that this kind of model helps to accelerate and capitalize on that.

DR. CROSSON: Craig, I apologize. You had volunteered, so go ahead.

DR. SAMITT: No worries. I think Mary said it beautifully, and I would also completely underscore the imperative for model 2. And the reason why I would is -- and, actually, I think the goals are wrong, by the way. I mean, I think the goals that I would underscore are not these. These are tactics. I think the goals are we're trying to improve accessibility and desirability of primary care, is really goal number one. And goal number two is to improve care coordination and quality of care.

And the reason why I underscored model 2 is model 1 does not accomplish really either of the goals. It's a minor redistribution, which certainly does not move us anywhere in the direction of population health or care coordination. I think only as we move in the direction of model 2 do we actually make substantive improvement in that regard.

And I certainly also have comments on magnitude and distribution, but I can hold that until we get to that point. But, absolutely, model 2 is the way to go.

DR. CROSSON: Sorry, but I'm going to try to keep it -- so I'm seeing a lot of bobbleheading around model 2, so let's -- right. Let me just for time -- let me ask for people who have a model 2 and a different point to make or who are in favor of model 1.

So, Kathy, Bill, Alice.

MS. BUTO: I'll do it quick.

I'm in favor of model 2. One of the things I would ask us, as we develop this model, to think about is broadening the things that are in partial capitation.

So, if one of our goals, as Mary was saying earlier, is to improve practice, et cetera, there are areas

where physicians, I think, could even make, in a way, more money by reducing utilization of some of the ancillaries that right now are just billed separately. And I think we want to look to giving them some incentive to doing that. How we do it, I don't know exactly, but that's one.

Back to Craig's point about our basic goal being increasing the appeal and the traction of getting into primary care, I would think about this model as being surrounded by other benefits, that if you're -- I don't know if we're going to make this mandatory or operational or voluntary, but CMS and Medicare has a lot of flexibility to reduce paperwork, improve payment quickness. There are things you can do to make providers' lives a lot easier, so make it more attractive than just changing the payment by surrounding it with other things.

Maybe you've got greater flexibility on telemedicine by definition. There might be things that other physicians couldn't get but if you're in this arrangement would attract you to it because it has a lot of other benefits to it.

DR. CROSSON: Thank you, Kathy.

I was actually wondering earlier where you were

going with that and whether you were talking about downstream costs because I agree with that point.

Bill.

MR. GRADISON: I think it's really important not to get too carried away about the benefits of this proposal. I suppose number two, but I'm not sure it's the answer to a beneficiary's prayer.

Let me call attention to our own document on page 27. Basically, it says, referring to our earlier recommendation, that the $2.60 was not considered enough for practices to make substantial improvements in care coordination activities and technologies that would significantly transfer the delivery of care. I want to elaborate upon that.

But the next sentence, which relates to the question of practice requirements is, I think, more significant, and again, I'm reading: The Commission was also concerned about the lack of evidence showing that practice requirements improved outcomes, such as higher quality or lower health care spending. Now, if that's true, then we have to -- why are we doing this? I think Craig's point is the place to start, without necessarily

assuming that the changes we would like in terms of outcome will necessarily be forthcoming anytime soon.

I am not bringing this up to recommend that there be mandatory practice requirements. I would make the point, however, that the various practice requirements that are listed in our document include management of care transition, medication reconciliation, coordination, dah-dah-dah, the very things we want. We're saying in the document that they're not necessarily related outcomes. So I'm just saying let's be careful how we package this thing.

DR. CROSSON: Thank you, Bill.

I'm sorry. Did I miss somebody? Okay. I had Alice and Jack, I think.

DR. COOMBS: So, as I was reading the chapter -- thank you very much, Julie -- the question I had when looking at the two different models is not -- it's more when. I want to remind us that we're replacing the PCIP. We're actually replacing something that we think needs to continue, but in that replacement, we're actually moving quickly to something that I think it takes a lot more time to develop some of the things of the uncertainty. As we talked about this, even though the visits may increase,

you're taking a hit on each one of those visits for comorbid conditions.

So my whole issue is that you fear loss greater than you desire gain at $2.60, so that's the basic line. I think going forward, I think that model 2 is a good thing, but the question is when. Our strategy was replacing the $2.60. So we've graduated to the Cadillac model very quickly and added $2.60 to that, so that was my concern.

DR. CROSSON: Well, we're not -- we haven't talked about the amount yet.

DR. COOMBS: Okay, okay.

So, I mean, before, when we had our previous discussion, that was --

DR. CROSSON: That was --

DR. COOMBS: That was the assumption.

So my question is -- and then I'm going to be honest with you. I'm going to be real, okay? If I was an internist and I saw this coming at me like this and all the questions that I have, I would say, "That sounds like a good plan for someone."

[Laughter.]

DR. CROSSON: Jack.

Are you raising your hand?

DR. CHRISTIANSON: Yeah.

DR. CROSSON: I'm sorry.

Yeah, Jack.

DR. HOADLEY: I mean, I think I'm comfortable with this notion. I like the arguments that I've heard around it.

I guess one of the things I'm trying to think about is what would this look like in the sense of -- I mean, I don't think we're thinking that 100 percent of Medicare beneficiaries are going to end up having their care managed through this model, and I think that's okay. So you've got a combination of the people -- I think Rita raised this -- who get their primary care through their cardiologist, their endocrinologist or whatever, depending on the particular chronic condition that they're dealing with. We've sort of left them aside, and so they would not potentially have a primary care physician, so no change would be going on. That's probably okay for something we're trying to move forward.

We have another set of beneficiaries whose maybe use of care is minimal, and they're not really doing sort

of a routine use of a primary care provider, but instead are dealing with things as issues come up.

So I think I -- just I'm trying to -- it's almost like a clarifying question of, is that in fact the way we see this, that some percentage, 60 percent, 40 percent or whatever of beneficiaries will end up having one of these attestations -- or whether we do it formally or not is still an open question -- and getting money moved around as a result and there's some other subset of beneficiaries for whom this simply won't happen?

DR. CROSSON: Well, I mean, I'll answer it, to the extent that -- I mean, again, we're sort of starting out. We're not really starting out, but we're starting out in a new direction. If this were to work, my sense is it could be expanded. It could be expanded in a number of ways, type of practitioner for sure, but also -- I mean, I think the fact that some family practitioners, but many internists, practice both internal medicine and a subspecialty, and so I think my sense is that this could be potentially broadened once the point is proved that it is working potentially.

DR. HOADLEY: And the internists under the PCIP

rules, many of them would not qualify, some would, and so, like you say, you could move those percentages, those rules at some point later to do it. So, I mean, I think that's a -- I just think it's something, a good framework to keep in mind, that we're not necessarily moving 100 percent of the population in this first phase if we were going to do this.

DR. CROSSON: Jon.

DR. SOMERS: I can add it's 24 million -- or 23 million beneficiaries that saw one of these eligible primary care providers.

DR. CHRISTIANSON: I just wanted to say that I agreed with everything that Bill said. I think we don't want to oversell this. If we really think the problem is better care management, we should figure out a way to pay for better care management. This is kind of a trickle-down theory of better care management. Maybe we don't do that because we don't know what works. That's what we thought a few months ago. So I agree with you, Bill. I think that you're right on.

I think the best chance of getting better care management and so forth is probably continuing our support for accountable care organizations, which seem to me to

provide better overall incentives to use primary care physicians efficiently and so forth than this.

But, having said all that, of the options available, I think model 2 is fine.

DR. CROSSON: And, as we talked about in July, we have to work on the Ferrari and the Mustang, and I certainly agree this is Mustang work at the moment.

Okay. So -- Kathy.

MS. BUTO: Just to Jon's point, I mean, Jon, is there any reason why this couldn't -- if model 2 were something we could make -- seem workable, why wouldn't an ACO be able to get paid essentially per-beneficiary payments for their -- that might simplify.

DR. CHRISTIANSON: I don't know. I suppose they could. My only point is to agree with Bill that overselling this is a way of sort of accomplishing other goals rather than just sort of narrowing the fee schedule. It makes me a little bit uneasy, I guess.

DR. CROSSON: Mary.

DR. NAYLOR: I do want to clarify because I think this is really important, what you raised, and so maybe

it's the language.

There is a pretty robust body of evidence that many of the care practice requirements, 24/7 access and so on, really get to better access, get to better care. So I'm not sure what the language in the chapter was, but I think that we should not -- and we have many practices throughout the country that are going through this transformation. The patient-centered medical home relative to traditional fee-for-service is demonstrating absolutely better access, better quality, and better performance. So I don't think we're as -- I actually think what we're trying to do is then to create the payment model that motivates that.

When I said practice requirements, I really felt that we shouldn't be saying what you should do as a practice versus you, but rather we should hold you accountable for using the right set of tools to get to performance. But there's a very robust body of evidence, and I think -- and a lot already going on throughout the country in primary care transformation.

DR. CROSSON: Okay. Could we put up either -- sorry. Mark? Did I miss -- Rita.

DR. REDBERG: I just wanted to add my agreement with model 2 and what Jon and Bill raised because I am concerned this -- while it does accomplish some rebalancing of payment, it doesn't accomplish care coordination in particular.

I mean, I see patients in cardiology that were seen by, I think, these high-volume primary care practices. I mean 20-year-olds who had echoes for dizziness, and I'd say, "And what did your doctor tell you about this test?" And they'd say, "They told me I should come see you." They didn't need to be seen, but I think in this -- so we wouldn't want to encourage that.

DR. CROSSON: Right. And I think Kathy was getting at that a little bit earlier when she talked about potentially rolling in some sort of risk for downstream cost. That gets more complicated, but it moves us further in the right direction.

Okay. So could we put up, let's say, slide 12 or one of those ones that has a chart on it? This doesn't show the whole range that we had in the pre-reading, but I would like to get a sense from the Commission. Since we seem to have an overwhelming consensus in view of model 2,

we'll move ahead with that.

In terms of the amount that we're talking about, we currently have $2.60, with all the consequences that fall from that.

As we've heard the discussion here and recognizing that we are potentially fixing part of the system that could be replaced by another system, but, in the meantime, we're fixing this system that we have, where are people thinking?

And, Craig, I'd ask you to start.

DR. SAMITT: I mean, I've underscored before that the $2.60 from my point of view is not substantive enough. Although this is the point where I think others have comments on the fact that we're automatically assuming that the way to fund this transformative approach to primary care is we need to take from specialists to give to primary care. The reality, though, is that if you do shift to per-beneficiary payment, the real opportunity is not necessarily just in per-unit reimbursement in the specialties. It's total utilization.

So, in the hands of primary care or practice that isn't on a treadmill and actually has the opportunity to

say, "Should I refer to this cardiologist? Should I order this test? Should I stay later to make sure that this patient doesn't get hospitalized?" the value from that is more than enough to fund sufficient additional primary care payments, in the absence of redistribution from specialty to primary care.

So I think $2.60 is too low. It needs to be high enough -- and I think there are two parts here. One is, what additional funding needs to flow to primary care, and then what percentage needs to shift to per-beneficiary payment? It needs to be enough that the model does not default back to making it up on volume, which I think most would say needs to be in the magnitude of 20 percent or so. That 7 percent is not sufficient to drive sufficient change in behavior.

DR. CROSSON: So now you're talking about the percentage of per-beneficiary payment, 20 percent?

DR. SAMITT: Per-beneficiary payment, I think needs to be at least 20 percent, if not higher, and then we could pick any of a magnitude of percentages in terms of how much more to supplement primary care. I think if you look at some of the more advanced direct primary care

models out there, their total compensation is in the range of 20 to 40 percent more per beneficiary. And this isn't just the shift from a fee-for-service to per-beneficiary payment. This is an additional payment per beneficiary as well to fund the additional steps and activities that the practice would take to reduce downstream utilization.

So, if you're spending -- let me give some statistics. If we estimate that we pay primary care 6 to 7 percent of total cost of care for primary care, but in the hands of a high-performing primary care practice, you can reduce total cost of care from 10 to 20 percent, you have quite a ways to go in terms of increasing per-primary-care-physician reimbursement of per-beneficiary reimbursement, far more than $2.60.

DR. CROSSON: I completely -- I totally agree with you in terms of management of the full health care dollar. There's no question about that. We have a more limited proposal here that we have to deal with.

So what I heard you talk mostly about was the percentage of payment that shifts to per beneficiary, and I personally would agree with that as well. But I still --

Just one second, David.

I still think we need to say, if we think $2.60 isn't enough, where do we think we ought to be on that transfer ladder or whatever you want to call it?

David.

DR. NERENZ: Well, on this point, I really now question the numbers in the left-hand column. The second bullet on top says 40 percent is now allocated to partial capitation, which would be well above Craig's threshold of 20. And that's part of certainly my reason for favoring two.

It seems odd then that the numbers in the left-hand column here are exactly the same as the same equivalent column on slide 8, which is model 1.

So are we really talking $2.60? Or are we talking some much bigger number.

DR. CROSSON: I think we're talking the size of the payment pool, and then we're talking about the degree to which it's divided into fee-for-service and per-beneficiary payment, two separate things.

DR. NERENZ: Well, but it may be a vocabulary question. In model 2, is the term per-beneficiary payment synonymous with partial capitation payment or are those two

different things?

DR. SOMERS: Yes, so up there, the 32 percent -- is that the number you were looking at? That is the share paid on a per beneficiary basis and includes both the $2.60 per month plus the 40 percent that you would take from fee-for-service and move over to a capitated payment.

DR. NERENZ: Is that 40 percent number in that table?

DR. SOMERS: It's what gets you to the 32 percent.

DR. NERENZ: But that dollar amount is not in that table?

DR. SOMERS: No.

DR. NERENZ: That's okay. That’s okay. I’m worried we’re getting -- you’re sort of asking about is that $2.60 the right amount. And at least in my head, you’re asking me is that the right amount for the partial capitation. But that’s not what we’re asking.

DR. CROSSON: No, no, no. We’re asking about the size of the primary care pool. And at the moment, we are talking about a transfer from other specialty.

DR. SAMITT: Yeah, I guess if I were to modulate

the proposal I would start, at a minimum, at the $5.20. So I think the 13 to 14 percent increase -- from a model 1 perspective I know we're talking apples and oranges -- to sort of more in the magnitude of what I've done historically in the organizations that I've led.

So $2.60 is too low. I would start, at a minimum, at $5.20.

The other thing that I would argue is that, again, as you also shift to per beneficiary payment, the funding doesn't necessarily have to come from other services, specialists. It can potentially come from foregone downstream utilization.

DR. CROSSON: I absolutely agree with that. And as we potentially build this in the future, as Kathy suggests, we may come back to that issue in terms of what is at risk in that primary care payment. But I'm still --

DR. MILLER: I am going -- because this one has gone around the merry-go-round a couple of times. I'm going to say something.

To Craig's point, while I believe that that is an absolute potential and I believe results have been seen in certain types of systems, remember this is Wild West fee-

for-service and you may not -- you know, the contents may settle. Okay? And so you may not get quite the same effect. So that's the first thing.

And I think if you don't do a dollar trade here, you will be scored as a cost. CBO will go at this and won't give a lot of love to the yes, but you'll get a management on the total dollar.

The second thing I would say, as much as I like these ideas of there should be some downstream accountability -- back to Bill and back to Jon -- there's a lot of noise here when you have an individual practice. And so the ability to measure that, even if you knew what you wanted to measure, will be somewhat limited.

So I hate to be the wet blanket here, but keep those two thoughts in mind as you go down this road.

MS. BUTO: But Mark, on that point, you could go after overpriced procedures or some subset. It wouldn't have to be an across-the-board tax on every service. In mean, there are a number of ways that you could go at this that are scorable.

DR. MILLER: Absolutely. And I did not mean to imply you couldn't get it out of other parts of the fee

schedule, although there was -- and I don't know what your judgment is on this, Kevin, in particular. The Part B reg, they're required by law to come up with 1 percent of overpriced procedures. Well, that's what they were required to come up with. They came up with 0.23, less than three-tenths, and then had to take the rest of it as just an across-the-board.

So at least -- you know, I am theoretically completely with you. And in fact, so is the Commission. The Commission has said that publicly, that that's the way to go. So your logic is sound. How much we can actually get our hands on....

DR. SAMITT: Can I just make one other comment, which is we took off the table, I think when we were talking about small numbers and we were talking about model 1. We said we wouldn't tie any of those amount to performance related metrics.

Although as we think about more model 2, we may want to revisit that. In fact, this is an area where we very much can learn from industry, whether it's my current organization or others that have done this. That there's no reason why we can't tie a percentage of -- a portion of

the per-beneficiary payment to some key performance measures that measure quality or efficiency, et cetera.

DR. CROSSON: Now I feel the need for a caution similar to Mark's, which is we're not trying to redesign a small version of an ACO here; right? I mean, that's what you and I both believe, or something like it, is the model. Arguably, we're trying to fix, for a while, a different part of the payment system and specifically fix it in such a way that we resolve a long-lasting problem of disparity of payment among specialities.

So we could -- while I believe all of what you're saying, and I think we can find ways to do that perhaps here, we don't want to necessarily over-design what we're doing here.

So I know it's getting late and people are tired and we're running the risk of not thinking this through properly here, but we have -- I sound like an auctioneer here -- we've got $5.20 on the table. I mean, do I hear arguments for sticking with $2.60? Or do I hear arguments for going more aggressively up to a higher number? Or are people, because of their general lassitude, thinking that $5.20 is modestly increasing the amount of money that's

paid to primary care physicians now through model 2 is where we want this to go?

DR. REDBERG: Jay do we have any data on how this would change physician behavior or incentives? The kind of magnitude of -- because I thought about it when I was reading the chapter. I thought well, $2.60 doesn't sound like a lot, but it's per beneficiary so if you multiply it by --

DR. CHRISTIANSON: Again, if we did it probably would be out of date because it's got to be filtered through the organization. So it depends on how the organization the physician works for decides to change the physician incentives when the payment changes.

I know all physicians don't work for organizations, all primary care docs, but an increasing percentage do. And so it takes a while to get something like this in place and then it takes a while for people to respond. Again, it's not just how a physician would respond to this. It's an organizational response.

It's very hard to figure that out at this point.

DR. CROSSON: But you can make a bit of your own judgment here. If you look on the slide, we're talking

about $7,708; right, on average. It will vary, but on average. And we're talking about what was the average salary, $183,000, or something like that? $220,000 or something like that?

I mean what is that, 3.5 percent? I mean, that's more than it was before.

This is not going to -- and I'm going to make a couple of comments in a minute. This is not going to solve this problem.

DR. CHRISTIANSON: And that's if it all gets passed through. DR. CROSSON: Yes, Jon, if it all gets passed through. If it all gets passed through.

But anyway, even if it all gets passed through, it's hard to believe that this is going to change the mind of a senior medical student with $400,000 of debt in terms of what career that individual chooses.

But we have an expiring additional payment that is currently being paid to physicians now. It's going to lapse. We want to replace it with something as opposed to necessarily waiting for the larger solution. And I want to speak to that in a minute, but --

MS. BUTO: What is the chronic care management

fee add-on? Because that apparently is not --

DR. CROSSON: It's a lot more. What is it?

DR. SOMERS: It's $42.

MS. BUTO: That has not attracted, it sounds like, very many physicians to this.

DR. CROSSON: It’s not been taken up, but my understanding it’s not been taken up because of regulatory complexity surrounding it. Is that right or wrong?

DR. SOMERS: Yeah, there's been small surveys of providers. They will say things like the beneficiary there has to pay a copayment on the $42 bill and they don’t want to ask their beneficiaries to pay a copayment on services that they don’t see, that aren’t face-to-face.

The other -- I think the complaint is that you have to bill 20 minutes of behind-the-scenes work per month for that bene, or you have to have 20 minutes, and that it’s difficult to keep track if you spend five minutes here and five minutes there, and then maybe you spend 17 minutes that month but 45 minutes the next month. And so that makes it difficult.

But there’s also, in some small surveys, a large number of providers in small surveys weren’t even aware of

the new code. So it could also be something that grows over time, being that this is the first year.

DR. CROSSON: I'm going to suggest, we're going to have to come back, obviously, in March?

DR. MILLER: I don't know. We don't know yet. We've got to look at the schedule.

DR. CROSSON: We don't know yet. We're going to come back at some point. We're going to work on model 2. We're going to work on a range of payment which is more than $2.60, somewhere between two and four times that. I'm arguing; right?

And we are going to bring forward, as a consequence, those additional issues which are most salient at that point, including the question of attestation or consent and how that would work, potentially practice requirements -- I didn't hear a lot but I did hear some for that. Potentially performance measurements, potentially the range of risk that we're talking about although I think we may be limited somewhat there. And the question of risk adjustment.

And we'll take another look at that. We have closed the circle to some degree here but not completely.

And I think, and I just want to make some closing comments here. I think we've heard a number of people say -- and I believe this -- that this is not the ideal solution for the problem we're trying to solve, either quantitatively or qualitatively. There are other things at play, including the development of alternative payment models and ACOs and other things that will have either a direct potentially or indirect effect on payment levels and incentives for physicians choose a career -- physicians and other health professionals choosing careers.

Over the last week or so, I went back and did some reading from 1988 -- yeah, I was alive then -- with respect to the RBRVS system. The thinking of Bill Hsiao and the researchers from Harvard Public Health School, in terms of what problem they were trying to solve at the time, and also what expectations they had from the development of this RBRVS model.

Not entirely, but in part -- ironically -- it was to solve this problem. Because the belief at the time was, in 1988, that the disparity in payment between primary care and specialty care was too much and it was having an adverse effect on beneficiaries and on physicians in terms

of their choices of life, career and profession.

It was the belief at the time that the institution of RBRVS would solve, at least in part, that problem. That has not occurred. In fact, what has occurred -- and it's not necessarily the fault of the model, but I think potentially in part it is, that the opposite has occurred and the problem has at least persisted and has gotten worse.

So my perspective here is that it is entirely within the range of this Commission over time, when we can do that -- and we're talking about a little later -- to ask the question "is RBRVS still, at this point in time, the best model for physician payment?" To examine what was intended at the time, some nearly 30 years ago, ask if that has occurred and if it has not, why not? And begin to look at potential alternatives.

We won't get to it this year, but my hope is that we will get to it -- or something like it -- next year.

So with that, Julie and Kevin, thank you very much for your work and we are going to move ahead. We are about 20 minutes behind but I think we'll be able to catch up okay.

[Pause.]

DR. CROSSON: Okay. We have had a number of comments from Commissioners and others, interest on the Hill, for example, for some time about the growing development of telehealth and in all of its manifestations and ramifications. So this is going to be our first formal look at that, and I think it is going to be primarily informational but should help us think about where we want to go in the future.

And we have the other Zach.

[Laughter.]

DR. CROSSON: Zach Number 2. Amy, Ariel, and Jeff playing clean-up or something, backup in the back.

So who is going to begin?

MR. GAUMER: I will.

DR. CROSSON: Zach, take it away.

MR. GAUMER: Okay. Well, good afternoon. In this last session of the day, we're going to talk about telehealth, as Jay just said. Many of you have expressed interest in this topic within the last year, and we have also seen an increase in congressional interest. In the last couple of years, there has been an increase in the use

of telehealth services across a variety of payers. Some believe this service may provide opportunities to expand access and convenience of care, improve quality of care and outcomes, and reduce the costs of care.

The goal today is to provide you with a foundational knowledge of telehealth services and to gather your guidance for further analysis. We will describe how telehealth services are defined, what telehealth services Medicare covers and their utilization. We will describe the extent to which telehealth services are being used in the non-Medicare setting and identify some general barriers to telehealth expansion. We will also describe to date what we know about the efficacy of telehealth services, and finally, to aid your discussion, we have a few questions for your consideration.

There are various types of telehealth services in operation today. The American Telemedicine Association defines telehealth very broadly, as you can see on the slide above. What we have found is that telehealth services include an assortment of combinations of services, modalities, and technologies.

The category on the slide above that may require

a little explanation is the modality circle. The ATA identifies four modalities or delivery mechanisms. These include hard-wired networks linking facilities within health systems, point-to-point connections which use external networks to link providers and patients, monitoring centers which link providers directly to many patients at once, and free-flowing Web-based communication.

To create a telehealth program, one might identify what service will be provided to patients, then what modality, and then what technology will be used to deliver the service.

For example, we have observed several programs where ICU services are delivered using an established telecommunications network within a hospital system, and the technology being used is two-way video. By contrast, other programs deliver basic primary care services using external networks, or the point-to-point modality, through basic technology such as the telephone, smartphones, e-mail, and text.

The key point here is that telehealth comes in many shapes and sizes.

Medicare currently covers telehealth services

under three different areas of the program. Under the fee schedule for physicians and other health professionals, Medicare covers a limited set of telehealth services on a fee-for-service basis.

This coverage began in 2001, with passage of the Balanced Budget Act, and has evolved in several ways since.

The fee schedule currently covers telehealth services if they originate in rural areas or at one of several different types of facilities. The beneficiary's home is not a permitted originating site. There are no restrictions on the location of the distant site, which are defined as where the consulting clinician is located.

Payment is based on the site. Originating sites receive a flat facility fee payment of roughly $25 for each visit. Distant sites receive 100 percent of the fee schedule amount. Medicare permits two specific types of technologies, two-way video, and only in isolated areas what is called store-and-forward technology.

CMS largely determines which fee schedule service codes are covered as telehealth services. These currently include general services like E&M visits, or general well visits, and more specific services like psychotherapy. And

these are listed in the mailing materials as well.

Telehealth is --

DR. CROSSON: So, Zach, the point here is that in terms of modalities compared with the broad category of telehealth, the covered modality is quite a small segment of all the potential telehealth modalities?

MR. GAUMER: That's correct.

DR. CROSSON: At the moment.

MR. GAUMER: Mm-hmm. Correct.

Telehealth is also permitted under the Medicare Advantage program, where plans have the flexibility to provide any type of telehealth services they choose, but they are currently considered extra benefits and therefore not included in plan's BID amounts.

Finally, telehealth services are also included as a part of several Medicare demonstration programs and in the proposed Next Generation ACO program. As a part of these programs, the fee schedule rules can be waived, and providers can receive fee schedule payments for the telehealth services they provide.

Okay. In general, there is very little use of

telehealth services in Medicare, but there has been growth in recent years. In 2014, about 68,000 beneficiaries used telehealth services, and that's about .2 percent of the population, the Medicare population. That year, there were approximately 175,000 telehealth visits to distant sites. However, since 2008, telehealth use increased rapidly, growing more than 500 percent per Part B beneficiary. In addition, overall spending on telehealth services is very low, at only $14 million in 2014. And the key point here is that despite the recent growth, telehealth remains a very, very small part of the program.

Now we want to shift to giving you some information about the types of facilities and beneficiaries that are using telehealth under Medicare.

The most common types of telehealth services provided in 2014 were for evaluation and management, psychiatric visits, and hospital consultations. Physician offices were the most common type of facility associated with telehealth visits. This was true for both originating and distant sites, but distant sites include a bit of a broader mix of facilities types.

Physicians, nurse practitioners, and

psychologists were the most common type of clinician associated with telehealth. We also classified several types of clinicians into the behavioral health physicians and found that many visits involved a behavioral health clinician. The combination of behavioral health clinicians and E&M services being common suggests that behavioral health clinicians are also providing E&M services.

Telehealth visits occurred in all 50 states and the District of Columbia, but Texas, Missouri and Iowa accounted for the largest share of visits.

The beneficiaries using telehealth services were younger, disabled, and reside in both urban and rural locations.

And as you can see on the left side of the slide, 62 percent of telehealth visits were for beneficiaries that were below the age of 65. In the middle of the slide, you can see that 61 percent of beneficiaries were eligible for Medicare through disability. By contrast, about 17 percent of all Part B enrollees were under age 65 and disabled.

In addition, on the right side of the slide, you can see that 63 percent of beneficiaries were rural and 37 percent were urban. Given that Medicare does not permit

telehealth in urban locations, the finding that 37 percent were urban may suggest that some of the claims are associated with either CMS demonstration programs, which do appear in the claims, or these claims could reflect inappropriate use of these services.

Overall, we identified nearly 85,000 telehealth visits for urban beneficiaries, and out of this pool, 44,000 visits had a distant site claim but not a corresponding originating site claim. And this may suggest that either folks are receiving care at home and not billing for it or there's some kind of inappropriate billing going on.

And now Amy will take you through telehealth that occurs on the outside of the Medicare program.

MS. PHILLIPS: Thank you, Zach.

Private insurers, employers, the VA, and technology vendors have demonstrated interest in expanding the use of telehealth services in recent years. Most of what we have been able to identify in our research up to this point is in the non-Medicare setting, focuses on basic provider visits as opposed to telemonitoring and other telehealth services.

Many large insurance companies have been offering telehealth services in the form of basic provider visits via telephone or two-way video to their members. Some large insurers require members to share in a significant portion of the cost of this service when provided through a telehealth vendor. Therefore, while telehealth is made available to some plan members, the majority of the cost of this service appears to be incurred by the member rather than the insurer. We believe there is variation from this for integrated health systems and other major employers.

Employers have also accelerated their use of telehealth services to reduce the cost of providing health care to their employees. In Towers Watson's survey of employers, they found that 38 percent of employers offered telemedicine as a part of their insurance benefit coverage in 2015, and they also found that 74 percent of employers plan to offer telehealth to employees in 2016. Looking at the nation's largest employer, WalMart, we see that they have implemented telehealth via their in-store health clinics that have been outfitted with video stations to enable their employees and store customers to conduct virtual doctor and specialist visits via two-way

videoconferencing.

Expansion had not been limited to the private insurance market. The VA has been experimenting with telehealth programs for over a decade. In fiscal year 2014, VA's telehealth programs served more than 690,000 veterans through more than 2 million online visits, with approximately 55 percent of these visits to veterans living in rural areas. We've seen the number of telehealth technology vendors also rapidly increase from 69 different vendors to 85 in 2015 alone, an increase of 23 percent.

Despite all of this expansion of telehealth, stakeholders have noted three particular barriers. Strict state-level medical licensure rules are a significant barrier to physicians and nurses who aim to operate telehealth across state lines. Clinicians must be licensed in every state in which they intend to practice, and each state has its own licensure requirements that typically do not permit partial or temporary licensure.

The VA also identifies training clinical staff and patients to use the technology and to manage data generated by telemonitoring services as both time consuming and costly.

Lastly, some stakeholders identify the lack of widespread broadband Internet access as a significant barrier to the growth of telehealth services.

The Federal Communications Commission reported that as of December 31st, 2013, 55 million Americans lacked access to high-speed Internet broadband services, which includes 53 percent of the rural population.

To date, evaluations of the efficacy of telehealth services to improve access and convenience for patients, improve the quality of care and patient outcomes, and reduce costs have shown mixed results. Existing research largely focuses on specific types of telehealth technology serving chronically ill populations, as opposed to telehealth programs that use various types of technology and focus on broader segments of a population.

In order to understand how telehealth programs or services can prove their efficacy, we have focused on three domains in which telehealth can have an impact on health care: by improving access and convenience, improving the quality of care and patient outcomes, and by reducing costs.

Telehealth services appear to improve access to

health care and convenience for the patients who use them. Telehealth is used by a number of organizations to extend care into rural areas. For example, some health systems use telehealth to extend the reach of their networks of hospitals to more isolated areas. To a lesser degree, telehealth has also been used to extend care into urban areas for chronically ill patients who are relatively isolated, as seen in several of the CMS demonstrations.

In addition, telehealth vendors, such as Teladoc and American Well, are modeled on the concept of creating convenience for patients by providing care outside of traditional settings at traditional and untraditional times. Evidence shows that patients appreciate the access and convenience these services offer, such as not having to leave work or receiving care in the middle of the night.

Research evaluating the efficacy of telehealth services or programs to improve the quality of care and outcomes have shown mixed results. For example, a study concluded that the use of telemonitoring as a part of a larger care management program for Medicare beneficiaries with congestive heart failure was associated with improvements in mortality rates of about 3 percent. By

contrast, a different study found that mortality rates were higher for patients over age 60 with multiple health problems that received only telemonitoring. This author found that mortality was higher at a rate of 14.7 percent for patients that had been in the telemonitoring group as opposed to the 3.9 percent mortality rate in the control group.

Lastly, this brings up telehealth's ability to reduce the cost of care, where we again see mixed outcomes in existing studies. Some research has demonstrated that telehealth services can reduce costs. For example, the previously mentioned study on patients with congestive heart failure also showed improvement in quality of care, concluded that telemonitoring was associated with spending reductions of approximately 8 to 13 percent per beneficiary. However, in a study, another stud, it was concluded that patients who had telemonitoring did not differ from similar patients who had not had telemonitoring in terms of number of subsequent readmissions and the number of days in the hospital.

Our initial research in telehealth services has provided some foundational information about Medicare

coverage and the use of telehealth, as well as a variety of information about what we know to date about the use of telehealth outside of the Medicare program and the efficacy of these services in general terms. Our plan is to continue our analysis, but we would like to gather your input on how best to proceed.

We have identified a handful of questions to guide your discussion about the direction of future analysis on telehealth. We ask what the Commission's goals are for this service. Are the goals to expand access and convenience, improve quality, or reduce costs? Or is it some combination of these goals?

In aggregate, the evidence to date about whether telehealth can attain all three of these goals or other goals may be perceived as insufficient. Is the existing evidence stronger for some telehealth services relative to others, or only in some specific applications as opposed to broader use?

The question of how expanding Medicare's telehealth coverage would impact program spending was posed to CBO recently. Their response was that the outcome of the cost analysis would depend upon whether telehealth was

defined as a service that substitutes for existing services or as a supplement to existing services. Their assumption is that if it is a substitute, telehealth may result in savings to the Medicare program. However, if it is a supplement, telehealth may result in additional programming costs. We would like to hear your opinion about whether telehealth is a substitute or a supplement.

Your responses to these questions may have implications for how Medicare pays for telehealth services and in which circumstances.

Thank you for your time. We look forward to your questions.

DR. CROSSON: Thank you very much. This is a very nice introduction to this area, which I think is of great interest to us and to others.

We're going to do clarifying questions in a second. I have one, actually. Maybe I should be asking myself or Mark. But when we're talking about future analysis and goals, et cetera, are we talking about telehealth within fee-for-service, medicine only, or including Medicare Advantage and the way it's being used and paid for, et cetera, et cetera?

DR. MILLER: So I think one -- I mean, there may be some very fundamental analyses or "what do you know about" or "could you go out into the private sector and find out what they're doing" kinds of questions that the Commission may have that we could pursue.

If you enter the discussion of what to do in the payments systems, our middle name, as it were, you could think about a path that goes into fee-for-service, but think of the usual issues in fee-for-service, kind of the Wild West volume issues, and also define the service, who can get it, who can do it, those types of things.

The other way your thinking could go is, could you create or allow more open-ended telehealth in certain payment services? So, if you were to be in a two-sided risk ACO, you might say, okay, anything goes in telehealth or in MA, as the case may be.

And to your very narrow question, I would say MA should be included in the conversation.

DR. CROSSON: Okay. Clarifying questions. Starting over here with Cori, Jack.

MS. UCCELLO: I think you've already answered this, but whenever the chapter, I think, make clear that

there was a big share of providers on both the originating site and the distant site who are behavioral health-related, but just a small share of the services were psychiatric in nature, it sounds like a big share of that was in E&M services. So it's still a little confusing to me why you would have a behavioral health provider on both sides.

MR. GAUMER: Well, I think this is the first time we've seen the data. We've been looking at it a little while. Our impression here is that -- and I'll say we haven't done any kind of conversations with providers that are actually giving this service or providing a service as much as we can. But it appears to us as though we have folks that are being labeled as behavioral health clinicians, and that category we created makes up psychiatrists, neuropsychiatrists, psychologists, and a few smaller specialties, are getting on the two-way video and essentially providing a behavioral health service. They may also be providing an E&M service which, except for the psychologists, are not prohibited from doing.

So, especially, I'm imagining if they're coming from rural areas, this is a possibility where you have one

doctor who's providing a couple of different types of service, but as I said at the beginning, this is not something that we have confirmed definitively with providers, and it's something that maybe we need to figure out.

DR. CROSSON: Okay. I had Jack, Rita, and then Mary. I'm sorry.

DR. HOADLEY: So, on slide 3, you had mentioned one of the services is the off-site imaging, reading the results by radiologists off site. I didn't see that listed in what Medicare allows. Is that not allowed by Medicare?

MR. WINTER: So we have to look into this more. If the radiologist doing the read is outside the United States -- and that often happens -- Medicare will not pay for that service because they don't pay for services provided outside the U.S.

Now, the question is, if the radiologists is, let's say, in Texas interpreting an image that was taken in Oklahoma, could that radiologist bill for the professional component? And my guess is probably yes, but we need to look into this more and study Medicare's billing rules in detail. So we can get back to you on that.

DR. HOADLEY: Okay.

MR. GAUMER: And just one more thing to add to that, the reason that this is on here also is that this store-and-forward technology that's permitted in Hawaii and Alaska, that could be imaging that's being sent somewhere else.

DR. HOADLEY: Yeah. And I know I've heard that kind of notion that the images -- that one efficient way to do images is to have providers in different locations who can be available at different times of the day or whatever, and I just didn't know how that worked out here.

Since there's a payment on the originating site as well as the distance site, are they both subject to cost sharing, the normal cost-sharing rules?

MR. GAUMER: So the answer is yes. They're both paying 20 percent on that.

In the last session, there was some conversation about really low cost sharing for like a $25 fee, so that would occur here too. But, according to the rules, they're both subject.

DR. HOADLEY: Right. Okay.

And I just wanted to be clear. I think you said

this. On the Medicare Advantage plans, those are treated as -- you said as extra services and therefore not part of the BID. So, even though Medicare Advantage plans can do a lot of this, it's because it's not typically a covered service on the Medicare fee-for-service side, that makes it an add-on service?

MR. GAUMER: That's right. And so the way Carlos has taught me and others have taught me, it comes out of the rebate.

DR. HOADLEY: Right.

MR. GAUMER: Okay.

DR. HOADLEY: So, again, when we're thinking about things that might come up on the MA side, that --

DR. MILLER: It's probably what we were thinking.

DR. CROSSON: Rita.

DR. REDBERG: [Off microphone.]

DR. CROSSON: Oh, okay. Was this a passed note, or was this verbal?

Mary.

DR. NAYLOR: On slide 11, you talked about -- I was interested in a chapter, Baker's work, and there were billing codes. CMS had billing codes in 2013 for

monitoring people, and then, all of a sudden, they jumped. States have adopted some of it, and I am wondering, given the positive, relatively positive findings, do we have any sense of why the billing codes were dropped?

MS. PHILLIPS: So, yeah, the billing codes were picked up by Medicaid, and it was part of a CMS demonstration for Medicare patients.

DR. NAYLOR: Yes.

MS. PHILLIPS: And CMS determined that the cost savings weren't big enough for Medicare to pick it up as a service.

DR. NAYLOR: So that 8 to --

MS. PHILLIPS: That 8 to 13 percent was before it was adjusted for the cost of the technology and training, which then -- and the CMS evaluation of the program became an insignificant savings.

DR. NAYLOR: Great.

And, secondly, in the next generation of ACOs, there is this piece that post-hospital, post-skilled nursing facility, home visits will not be able to be covered in the next generation. Any understanding of why that's the case?

MR. GAUMER: I'm not exactly sure, but I do recall what you're talking about. There is no post-hospital or post-SNF follow-up visit that is a covered service typically under telehealth in the home setting. I'm not exactly sure why, but there's generally -- it seems to be a reluctance to do home-based telehealth. Yeah.

DR. CROSSON: Despite the fact that 62 percent of the recurrent recipients are disabled; is that right?

MR. GAUMER: Yes.

DR. CROSSON: So, presumably, these individuals, many of whom are homebound, need to travel to some site where they can do videoconferencing with the originating site; is that right?

MR. GAUMER: That's the way it should work. I mean, that's the way --

[Laughter.]

MR. GAUMER: That's the way it works, yeah. Whether or not there's inappropriate billing happening out there, that's the way the rules say to do it.

DR. CROSSON: Thanks.

Clarifying questions? Kathy and then Bill.

MS. BUTO: Is there a concentration of the

physicians who do this on the -- particularly on the originating side but maybe also -- I assume that they go to certain referral centers on the other side -- and/or the patients? In other words, do certain patients use this service a lot, or is it pretty thinly spread just based on an episodic situation where somebody is, say, following up on a surgery and needs a consult or something like that? Do we have a sense of that concentration? Because there's so few -- I mean, the amount of money is so little, it just makes me wonder what's going on.

MR. GAUMER: So we've done a little thinking about that. In terms of the beneficiaries, there's 68,000 beneficiaries that use this service, 175,000 visits, so that's a couple apiece on average.

We haven't looked into kind of a frequency of the top 20 people or anything, but we have done that on the provider side, and we do see some groupings of providers that seem to be doing a lot of it.

I think we were curious to see what was going on in the urban setting, and there were some providers that were serving urban beneficiaries more than others, some in the thousands-per-year range.

MS. BUTO: And you mentioned mental health providers, physicians and others. I assume mostly others based on the shortage issue that seemed to be participating in this.

MR. GAUMER: Yeah. The few providers that we looked at that seemed to be doing a lot of telehealth seemed to be specializing -- well, I've only seen one specialist. There is also a couple that are more generalists. Yeah.

DR. CROSSON: Bill.

MR. GRADISON: I understand you're going to be trying to get more information from the VA. When you do, I'd be very interested to know this. I assume that at both ends of the call will be VA employees. I have understood to the extent, if there are examples, that they are non-VA people, in other words, where they would use this to bring in people who are not part of their ongoing regular organization.

Thank you.

DR. CROSSON: Clarifying questions. More?

[No response.]

DR. CROSSON: Okay. So we're going to have a

discussion now.

Why don't we put up slide 13. Here's a set of questions staff has asked us to focus on. Essentially, what we're trying to do here is help Mark and the staff to find future work in the area of telehealth. So we have -- I think Rita and Alice have asked to lead off. We'll start with Rita.

DR. REDBERG: So this was an excellent chapter and I think gave us a good overview of telehealth, which I think one would conclude is promising, needs more data, and is a lot of different things. I mean, the list is very long, and appropriately, because I think a lot of things do fall under telehealth.

And that the current data that we have right now, I would say is mixed. Probably because it's mixed and probably because it really depends on how you are using it, like you said, is it replacing current services, is it supplemental to current services, you know, and exactly what it is.

In our sort of overall grant picture of going towards alternative payment models and MIPS and what was mandated in MACRA, it seems to me that it doesn't make

sense to start talking about fee-for-service approach to telehealth because I don't think we could figure out all of this, what works and what doesn't. I think the things that do work are going to be more efficient, and then large organizations will want to use them. And the things that don't -- and so that our approach should stay within the bundled payment or ACO, what's listed here at the end and I think what Mark was talking about a little bit earlier, because there are potentials for efficiency, and there are also potentials for a lot of inefficiency. And I don't think we're in the business of sorting that out. I think we pay, and so we are paying for efficient care, and telehealth increases your efficiency. Then it would be paid for. So we can liberalize, like you said. It can be used, but I don't think we want to get into costing it out and into a really complicated formula that surely we would come to regret.

DR. CROSSON: So let me see if I can understand what you are saying. Are you saying you think that telehealth, as defined here, which is fairly narrow definition at the moment -- telehealth, as defined in the fee-for-service arena, is likely to represent additional

services? Are you saying that, or what?

DR. REDBERG: I would say, currently, what I can -- in the use of telehealth, I think it is additional services, but I think that's because it's right now we're operating more in a fee-for-service arena. But I think it has potential to replace services or be used instead of coming back into a doctor, you can talk --

DR. CROSSON: In a different payment arrangement.

DR. REDBERG: Right.

But I just think it makes a lot more sense to think about it in terms of an ACO model or a capitated, like a primary care payment. It could include -- if the practice wishes to use telehealth in whatever way they want to use it --

DR. CROSSON: Right. The broader definition of telehealth.

DR. REDBERG: Right. Then we could broaden the definition but not separate it out for payment. Does that make sense?

DR. CROSSON: It does. I just want to be clear what I thought you were saying.

First, Alice.

DR. COOMBS: I think it's wonderful. You guys did a great job.

I was thinking along the lines of the progression for critical care as an example of what they did in critical care. Initially, when you had a critical care patient, there were certain things included within this time frame to bill for. It's the minimum of 30 minutes, but included in that could be the discussion with a family, a family meeting, discussion of diagnosis and prognosis.

And so I was looking at this as a substitute specifically in the context of -- especially in that context, but also looking at the psych and mental health issues, I think that particularly can actually enhance outcomes, especially when you have patients with thought disorders and they need serial follow-ups.

In view of that, I don't know if we can do this, but certainly, some of the fees that we talked about earlier -- transitional care management, chronic care management -- if we could incorporate some elements of telemedicine within that capacity, especially diabetic management -- there are studies from England that talks about decreasing admission rates for COPD 50 percent, and

so they may be ahead of us in this spectrum in terms of being able to implement early on for the high-cost diagnosis, COPD, congestive heart failure, diabetes, and utilizing assistance, education, and having a real, real titratable effect, impact on patients.

There's someone who has a website called Patients Like Me, where the patients log in, and they have a capacity to -- you've probably seen it. They do some amazing things. And then there's another program where they give apps to follow patients along, and the patients can be keyed in for taking the antiretrovirals.

I think there's a lot of innovation here that could actually lead to better outcomes, better quality, and definitely improved costs. Why the data doesn't support it yet, I think there's probably so many confounding variables in some of the stuff that we've read.

The other piece of it is the regulatory barriers, and I was thinking about the VA. That you can work at any VA as a physician. If you work in Massachusetts, you can go anywhere, and so wouldn't it be a wonderful thing if there was some kind of regulatory relief for interstate practice. That's where we could probably make a difference

with that piece because it is burdensome to try to be able to practice from state to state. And I know Sue and I were talking about this earlier.

I think the other piece of this is rehabilitation. You can actually to telerehab, and wouldn't that be wonderful to cut the cost of some of the things that we're doing based on the telehealth? I think that's interesting.

The home health piece, I think is definitely a substitute, looking at patients on a daily basis. Those are some areas where I think we could be innovative, and we could take this to another level. There's a lot of opportunity here.

DR. CROSSON: So, Alice, one of the examples you mentioned, of course, was the UK, and one of the characteristics there is that, of course, it's a different payment system again. Some of the numbers you quoted, I believe absolutely, but I think one would argue that they're a consequence of a different payment system.

At least some of what you said, I heard was echoing what Rita had said and what I think Mark is thinking as well, that we at least have to divide this

question up into what can be done or should be done within the fee-for-service payment system, and then what can and should be done in other payment systems which contain incentives, both for improved quality and perhaps lower cost as well.

DR. COOMBS: So, for the fee-for-service, we've always talked about site-neutral kind of payments, from SNFs to IRFs to the LTCHs. This could be another option for rehab patients who are simplistic and straightforward. I mean, certainly.

DR. CROSSON: Okay. Just on the other question of the state licensure, there is a question that I know has been discussed at the National Federation of Medical Boards about national licensure. My sense is that that is not within our purview to work on?

DR. MILLER: It would be a reach, right. I mean, essentially, you would be saying that federal law or at least federal laws as it relates to Medicare preempts state law, and that's a fairly big reach.

And a lot of the underlying structure in Medicare kind of works like this. Medicare will pay for a

provider's visit to do these things as long as the state has licensed that provider to do that thing as opposed to the federal government saying, "Here's what that provider can do." So it would be decidedly going at the underpinnings and taking on a really big issue that's basically state rights.

DR. CROSSON: Has MedPAC ever testified at the Supreme Court?

DR. MILLER: No.

[Laughter.]

DR. MILLER: And we're not looking to.

DR. CROSSON: Okay. Where are we? So let's go down this way. Kathy, were you wiggling your fingers?

MS. BUTO: I've got to just pick up on something Mark said because it's sticking in my mind.

You know, although you're right about deferring to state licensing, all of the conditions of participation have stuff in there about a hospital has to have this many things and have these health and safety requirements, and, oh, by the way, you've got to have certified this and that and a license to -- dietician and so on.

So, depending on whether -- and I don't think

there are conditions that go with telemedicine, but if there were criteria for who a participating telemedicine facility would be, it seems to me you could add stuff about who's licensed to do it or who can actually be providing that service.

Are there conditions or anything like that?

DR. MILLER: I don't think so.

MS. BUTO: I'm doubting that.

MR. GAUMER: There isn't a lot that I know of. There's a list of types of originating sites that are permissible, but it's not linking.

MS. BUTO: But, on the other hand, not the consulting site.

MR. GAUMER: No. That's pretty wide open.

MS. BUTO: Yeah.

DR. CROSSON: Okay. So, again, we're focusing on where we would like the staff to be going, and I've got Craig and then David.

DR. SAMITT: I think this is a crucial topic that requires further exploration.

We often will talk about the fact that we should be looking toward the private market and how much they are

making a play into innovative approaches, and I think what you would find is organizations that are aligned around population health financially are very much interested in investing in the power of telehealth, and it's actually both a substitute and a supplement.

The reality is that if there is a more convenient alternative for a beneficiary to get a service, then they should not come into an office setting. They should actually have access to that at home.

And the supplement is if there would be a gap in care because the beneficiary wouldn't be able to get to a clinical environment, telemonitoring and the avoidance of an ER visit or an emergency visit is a supplemental service that otherwise would not have occurred.

So I think we somehow need to find a way to loosen the restrictions here. I know the reimbursement challenges, but it feels like we're going completely against the grain of other industries.

As I read the chapter, it's kind of like -- comparing to other industries, it's as if the old way was we would get in a car to go to Barnes & Noble to buy a book. Now the new way is we have to get in a car to go to

an approved Amazon.com facility to go online to order a book as opposed to going direct. So this makes no sense to me. If we should be connecting directly and finding a way to reimburse that in a manner that's going to reduce the cost of care, all the goals are relevant: improve access, convenience for the beneficiaries, and reduce costs. We need to find a way to understand how we can work within either the ACO world where we release restrictions in the ACO world because that's what ACOs will want to do or some other way within the fee-for-service chassis to allow this innovation to happen.

DR. MILLER: And I think some of my comments, when I was asked, go in that direction. Think about your conversation on the primary care discussion and, again, I think there’s a whole pile of issues there that are going to look different the next time we come back.

But let’s say you got to a resting point there. You could certainly say, within that capitated payment --

DR. SAMITT: Of course. [off microphone.]

DR. CROSSON: David.

DR. NERENZ: Just a couple of things. One now plays of Craig’s example about the Barnes and Noble.

It seems like we ought to look for opportunities for effective substitutes. The analogy might be an office visit where if the current state is the patient goes to the office and then has to sit in the waiting room and has to be checked in by a receptionist, taken into a room, temperature taken, put a gown on, all of that stuff -- much of that cost is taken away if it's a televisit. And presumably then the payment for Medicare for the tele-version of that could be less if the medical content is essentially the same.

Dermatology might be a good example of that where, rather than going into an office to have a rash looked at you just do it on a screen. But the essential work would seem to get done at less cost and therefore could be reimbursed at a lower rate. So that would just seem like an area of opportunity to look for.

Then the second thing is a question just on the state license thing. This is really a question, not a suggestion. Two examples, and let's use psychiatry now as the example. Let's say currently, a patient who lives in Ohio drives across the state line, sees a psychiatrist in Michigan in a traditional office visit. The psychiatrist

is licensed in Michigan and that care is delivered in Michigan. That's now.

Okay, so now in the telemedicine thing, the person stays in his or her home, the video connection is in their home. The physician is in Michigan, the interaction is exactly the same.

Is the problem that that care is now deemed to have been given in Ohio? Is that the problem?

DR. CROSSON: That's correct. That's correct.

DR. NERENZ: That seems odd to me. Is that a matter of some -- I mean, maybe nobody else thinks it's odd. I think it's odd.

DR. CROSSON: My understanding is, at least from discussions in California, is that's how the state licensing boards define care. It's delivered within their border. The patient --

DR. NERENZ: I guess I'm trying to split the hair. Does it depend on the physical location of the provider at the instant or the patient?

DR. CROSSON: It's where the patient is.

DR. NERENZ: Well, could that just be changed? I mean, who makes that rule?

DR. CROSSON: Each state, one at a time.

DR. MILLER: Each state.

DR. NERENZ: But they're all the same? Or all they not all the same?

DR. MILLER: I imagine there's some variation.

DR. NERENZ: Okay.

DR. CROSSON: And there are activities going on within states led by certain physicians in certain specialties and opposed by others to try to loosen that --

DR. NERENZ: I understand. Okay.

So that if that was going to change, it would change 50 decision units at a time.

DR. CROSSON: As things are currently set up, yes.

DR. NERENZ: Okay.

DR. MILLER: This gets into some of those same issues that there's the fights between physicians and nurse practitioners and -- it's all of that crowd. It's that same issue and sort of protecting turf, that type of thing.

MR. GRADISON: It never occurred to me that my doctor who has offices in Maryland and D.C. might be doing something wrong if he calls me in Northern Virginia where I

live and gives me some advice, the basis of which he -- or who phones in a prescription to a pharmacy which is also not in Maryland or D.C. But maybe that's a quaint --

DR. CROSSON: Bill, I don't know the answer to that because I don't know your physician. But I am familiar with how Kaiser Permanente works in this area. And to my knowledge, it's a little dated obviously, but to my knowledge the vast majority of physicians are licensed in all three jurisdictions for that reason. And that takes a lot of time and....

MR. GRADISON: Yes. [off microphone.]

DR. CROSSON: Jack.

DR. HOADLEY: I guess I have two thoughts. One goes back to the Medicare Advantage question. I guess I'm interested to know if there's any downside to changing the rules so it would give the MA plans more flexibility to provide these services within the benefit as opposed to as extra benefits? Or whether there's impediment, on the other side, to the way it works now? Maybe that doesn't really limit what an MA plan does in terms of implementing telehealth.

So if there's no problem to be solved, we don't

need to change the rules. But if that's becoming an impediment to MA plans, then that's something we should look at. And is there any other downside on that?

DR. CROSSON: My guess would be if you've seen one, you've seen one. It relates to the payment rates and the premium structure and the like.

DR. HOADLEY: Yes. And to the extent that plans are in different situations relative to rebate dollars and all those other kinds of things.

I mean, the other thing that seems like -- you know, we can talk about the things you can do with telehealth, and we all have many examples of those. The point, I think, that we heard in the discussion was that right now it sounds like CBO would score any kind of attempt to expand the ability to use telehealth quite possibly as a cost. And I think the challenge should be to think about -- you know, we talked about substitution versus supplement.

Are there means to broaden the ability to use it that would look at scorable at least as neutral -- not necessarily as savings -- but sort of what are the criteria that make it looks like it costs? Because as soon as you

say well, I can do that rehab follow-up in the home, well now that becomes in addition to what I already did. I already had the patient in the home health or in the rehab setting or in an in-person kind of rehab visits. And now I'm going to be able to bill for three more encounters that are done via telehealth, via the home, that I never billed for before.

So that seems to be why it often looks like it's a potential add-on to services. And I think if we can think about ways that you could allow more use of these services where there are useful services without it ending up creating the means to just add on more services, and thus more costs, I think that's the challenge.

Otherwise, you go to the route of saying well, let's do this within the ACOs or within the primary care capitation we were talking about, or things like that, where you don't have to deal with those obstacles.

DR. CROSSON: Or both. I think this is the core question here. Because we've heard a lot of support for the notion of the utility of this alternative payment models, or whatever you want to call it, including MA and ACOs and the like. And that seems patently obvious on the

face of it, as well as there being an experience base, as Craig said, in the commercial world now for that as well as in the MA world.

The question, I think here for the staff going forward, is is there an answer to your question? And what would it take? How would you arrange it in the pure fee-for-service environment to provide flexibility for care delivery in such a way that it did not create incentives for overuse and extra billing and the like? What would that look like?

And I think you've hit it right on the head.

MS. BUTO: It strikes me that maybe we could think about that because there are some services, like reading radiology images, that you're not going to overdo the utilization on. You'll either read them remotely using this technology or you'll do them some other way.

It just seems to me there might be services that are not now currently covered that you wouldn't be able to easily game. But it would sure make life easier for both the originating physician or patient and the receiving.

And then on MA, it strikes me that I don't see why telehealth should be paid out of the rebate if -- again

it falls in these categories of things that you're clearly substituting, you're going to use instead of an in-person visit to discuss an image or some other things that we might be able to identify. Maybe even mental health visits that occur with this frequency, that kind of thing, that it clearly is going to be a substitute.

So I don't think it's something we can't look at or ask the Secretary or suggest that the Secretary look at and try to identify, maybe using some examples. Get some comment on it, areas where it clearly makes sense, it's going to be a substitute, not really subject to abuse. I'm sure they can come up with a list.

DR. CROSSON: Well, in the context of again risk-bearing, or Medicare Advantage, abuse would look very different. Alice.

DR. COOMBS: I just wanted to add one other thing and that is when you have disabled patients who have to come in from home, sometimes there's an ambulance ride that's involved. So there's another situation where you have added costs just for the transportation alone.

DR. CROSSON: Well, yeah, that's why I was wondering before about the current state of affairs with

respect to beneficiaries who qualify under disability. Obviously, then they are not all homebound but some are homebound, perhaps a large number are homebound or are homebound partially and require extraordinary or expensive transportation requirements in order to get to the telehealth site, which seems to be counterproductive.

DR. HOADLEY: Or just to get to the regular site of care.

DR. CROSSON: Right, right.

DR. HOADLEY: It's not necessarily even substituting for home originating location but say okay, if they've got to go in to have something monitored on a regular service and it could be done remotely in that kind of situation.

DR. CROSSON: Okay, well I think this has been a preliminary but a good discussion. I think we have potentially two streams of work here. One has to do with telehealth as defined or as broadened in the area of alternative payment models, including existing ones and potentially others.

And then the second one, which Jack brought up and others have alluded to, is the question of -- Kathy

most recently -- is the question of perhaps in a narrower way, within pure fee-for-service payment, what could be thought of and designed that would not only not be scored negatively but actually improve quality and potentially improve the beneficiary care experience and maybe even save money or at least be cost neutral?

So maybe that's a tall order but I think those are the questions that I've heard so far.

So I think we've come to the end of today's session. Thank you very much for the presentation.

We have now reached the point in time where we have an opportunity for public comment. So if there are members of the audience who would like to make a public comment, please come forward to the microphone so we can see how many public comments we have at the moment.

[Pause.]

DR. CROSSON: So it looks like we have an enthusiastic crowd here. Let me just make a couple of points, and I think you may be aware of this but it's my job to make them anyway.

The public comment session is not the only or the best way to provide feedback to the staff and, through the

staff, to the Commission. There are online mechanisms, as well as through Mark and Jim and his staff, making appointments, and other ways of communicating, both in writing and in person with the MedPAC staff.

Having said that, this is a good opportunity so when you come to the microphone please give us your name as well as an organizational affiliation. We would ask you to limit your comments to two minutes.

I will turn my microphone off as you begin speaking and when the light comes back on, that's two minutes. Thank you.

MR. ZAMAN: Good afternoon, and thank you to the Commission for its work on these issues.

My name is Shahid Zaman and I'm commenting on behalf of America's Essential Hospitals.

America's Essential Hospitals is a membership association of 275 hospitals and health systems dedicated to high quality care for all, treating a disproportionate share of low-income and uninsured patients.

Our comments today focus on the Commission's discussion around telehealth and Part B drugs.

First, we appreciate the Commission exploring the

rapidly expanding area of telehealth. Telehealth services at essential hospitals have helped to increase access and improve health outcomes for our patients in both rural and urban areas.

Current Medicare reimbursement for telehealth services is limited in scope, both in terms of the types of services that are reimbursed and also in terms of geographical limitations on the originating site.

Therefore, the Commission should consider ways in which telehealth services can be appropriately reimbursed to expand access for all patients, not just those in rural communities.

With regard to the Commission's discussion on Part B drugs and the 340B program, we would like to emphasize the important role the 340B program has played in enabling essential hospitals to deliver coordinated cutting edge care to vulnerable patients. In the words of Congress, the 340B program was meant to enable providers to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.

Essential hospitals, which operate on an

aggregate negative 3 percent margin compared to positive 6 percent for all hospitals nationwide, have been able to harness 340B savings to coordinate care and improve outcomes for their vulnerable patient populations, including through initiatives aimed at reducing readmissions, ensuring medication compliance, and identifying high risk patients in need of ancillary services.

We would ask that going forward the Commission be mindful of the invaluable role the 340B program plays in allowing providers with limited resources to provide high quality care and wraparound services to patients.

We look forward to following the Commission's work on these issues. Thank you for the opportunity to provide comment.

DR. CROSSON: Remarkably accurate in time. Thank you very much.

[Laughter.]

MR. BRANDT: Good afternoon. My name is Derek Brandt and I'm representing the American Academy of Neurology as well as the Cognitive Specialty Coalition, which includes groups such as allergy and asthma, neuro-

ophthalmology, rheumatology, infectious diseases, endocrinology, and collectively we represent about 115,000 physicians.

When determining how to ensure access to evaluation and management services for Medicare beneficiaries, we continue to urge the Commission to not focus primarily on specialty designation but rather on the care being provided to patients.

There is no actual primary care services in the Medicare fee schedule. Our specialities bill the exact same codes as primary care providers. These evaluation management codes are for new and returning office visits, not for primary care services.

We agree that there is a crisis in primary care. But as mentioned a few times during the prior conversations, our specialties bill the exact same codes and have similar incomes as a result, and also have resulting recruiting challenges, as well.

Policies like those being discussed by the Commission pick winners and losers based on specialty designation that do not reflect the realities of patient care. The Commission’s own data shows tens of millions of

Medicare beneficiaries are not relying on primary care providers for their coordination of care.

So who are these patients? There are those with complex chronic conditions like Alzheimer's, ALS, Parkinson's, HIV, RA, diabetes, and are some of Medicare's highest cost, highest need patient base.

Yet the Commission continues to focus solely on primary care. Ultimately, we think it will send a message to students entering medicine that specialties like ours ought to be avoided. Why put the extra time and effort into specializing if the ultimate result is less reimbursements for treating more complex patients?

We urge the Commission to take steps to encourage fairness by incentivizing face-to-face time for all physicians that provide 60 percent of their time as evaluation management services.

Thank you so much for your time.

DR. CROSSON: Thank you very much.

MR. DAVIS: Hello, my name is Jeff Davis with 340B Health. We represent hospitals participating in the 340B program.

The Commission had a great conversation earlier

today about 340B and I just wanted to briefly comment on two points that were raised earlier.

The first was discussion of unintended consequences that could occur if Medicare reduced payments to 340B hospitals. We just wanted to make the Commission aware that we do have information, this has been documented by researchers in multiple reports, on how 340B DSH hospitals differ from non-340B hospitals. We know that 340B DSH hospitals treat nearly twice as many low income patients. They provide significantly more and a disproportionate amount of uncompensated care. They provide more unprofitable and specialized public health services. And importantly, as I think was mentioned earlier, they have lower outpatient financial margins than non-340B hospitals.

So all of this, taken together, really suggests that if you reduce the reimbursement to 340B hospitals and therefore reduce the amount of the 340B benefit, you will be really having a negative impact on the low income patients that are treated by these safety net hospitals.

So we think that this is important information for the Commission to consider before making any

recommendations in this area.

The second issue that was mentioned earlier was discussion of whether Medicare should be subsidizing safety net hospitals. We at 340B Health believe that whether 340B savings should be shared with Medicare beneficiaries should be viewed as a separate issue from whether those savings should be shared with the Medicare program.

We'd also like to point out that 340B is a Public Health Service program. It is administered by the Health Resources and Services Administration, not Medicare. And Congress established 340B, as was mentioned earlier, with the goal of stretching the scarce resources of safety net providers so that they could provide more services and reach more patients.

The mechanism that Congress chose to enable this goal was for the safety net providers to buy drugs at reduced rates but continue to be reimbursed at their standard reimbursement rates. So reducing Medicare reimbursement to 340B hospitals would be --

DR. CROSSON: Thank you for your comment.

MR. DAVIS: -- inconsistent with this mechanism. Thank you.

DR. CROSSON: Thank you for your comment.

DR. LUKE: Hi there. I'm Dr. Josh Luke and I teach at the University of Southern California's Sol School of Public Policy, and I've also been a hospital CEO and nursing home administrator for about 10 years.

I'm not here to advocate for any organization other than the fact that I'm passionate about serving seniors in the behavioral health community, as I've done for the last 15 years.

I just wanted to comment on some of the discussions that you've had today, and thank you for your service here because I see that same passion.

Having run a safety net hospital and also multiple nursing homes, when you talk about telehealth and remote monitoring, the numbers that were shared today -- and I thought that was a great presentation. In fact, each of them, I was really thrilled to see all the great work put into them.

I would really encourage you to look at those numbers as a floor. That's really probably the minimal savings. We're so new in this process of researching and implementing this technology in the United States. Someone

referenced the studies that have been done overseas that are showing significantly higher results and I think we'll see the same over time.

In a hospital and a nursing home, some of the unintended savings that's there is cutting the length of stay by two or three days, very hard to measure, very hard to put into numbers. Very hard to get a psychiatrist to come out to a nursing home oftentimes. Very hard to get a psychiatrist to come. In Los Angeles County last year, I filled in as an interim CEO in a safety net hospital. Very difficult to get a psychiatrist to come to the emergency department whereas telehealth could have solved the problem in a matter of about two hours.

Getting, however, investor-owned safety net hospitals to make the investment in telehealth equipment, just the initial investment right now, is really a challenge.

In terms of the primary care presentation that was made earlier, I just had a couple of comments. I was the chair of the provider advisory committee for CalOptima in Orange County, California 10 years ago when we tried to auto-enroll.

Literally what you can expect when you give physicians that type of autonomy in an auto-enrollment situation is what we saw, which you walk into your primary care physicians office, a senior does, and the sign on the wall said if you want me to be your doctor, sign here. No more details necessary. Ten years later, Los Angeles County is attempting the same thing for 300,000 Medi-Medi enrollees and we're seeing the same behavior.

So I would just encourage you, as you look at those as it pertains to autonomy for physicians in the process, to keep that in mind.

Thank you very much for your time.

DR. CROSSON: Thank you very much.

MR. JAGODA: Good afternoon. My name is Jonathan Jagoda. I am the Director of Federal Government Relations with the Federation of State Medical Boards. We represent all 70 of the state medical and osteopathic licensing boards of the United States and its territories and I think you for the opportunity to comment.

The FSMB supports the safe and accountable use of telehealth and considers telehealth to be equivalent to the practice of medicine and, thus, should be held to the same

standard of care. The FSMB supports the state-based medical licensure and regulatory system, which requires a physician to be licensed at the location and the state of the patient. This time-tested and practice-proven system protects patients across the nation.

In accordance with this principal, the FSMB and the state medical boards that we represent support license portability, which is needed to expand access to care, streamline medical licensure, facilitate multi-state practice, and enable telemedicine in a safe manner. As such, state medical boards have begun to implement an interstate medical licensure compact, a new alternative pathway to allow for physicians to be licensed in an expedited fashion while ensuring patient safety across the country.

We look forward to sharing more information with you and work together with the Commission to support medical license portability.

DR. CROSSON: Thank you for your contribution.

MR. VICE: Hello. I am Elliot Vice, Director of Government Affairs for the National Council of State Boards of Nursing, and I hopefully will win the award for brevity

today because I echo Jonathan's comments.

We started working with our boards on an interstate compact for RNs and LPNs and LVNs back in 1997 and currently have 25 states in that compact. Recently, it was revised and we will be going into states next year to add more of them to this compact.

Additionally, I would note that we are putting together a compact for Advanced Practice Registered Nurses, as well.

I really hope that you, as a Commission, see that state boards of nursing really are trying to lead the way to support license portability and telehealth.

To that end, I hope that the staff and the Commissioners will use us as a resource moving forward whenever you are discussing state-based licensure concerns.

DR. CROSSON: Thank you very much.

Seeing no one else at the microphone, we are adjourned until -- yes, 8:15 tomorrow morning.

[Whereupon, at 5:12 p.m., the meeting was recessed, to reconvene at 8:15 a.m. on Friday, November 6, 2015.]

MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, November 6, 2015
8:15 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
KATHERINE BAICKER, PhD
KATHY BUTO, MPA
ALICE COOMBS, MD
WILLIS D. GRADISON, JR., MBA, DCS
JACK HOADLEY, PhD
MARY NAYLOR, PhD, FAAN, RN
DAVID NERENZ, PhD
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
SUSAN THOMPSON, MS, RN
CORI UCCELLO, FSA, MAAA, MPP

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AGENDA PAGE

P R O C E E D I N G S

[8:15 a.m.]

DR. CROSSON: Okay. Good morning, everyone. Welcome to the bright and early second day of the MedPAC meeting. Again, we have an important agenda this morning and both presentations, I think, containing a good deal of detail that we want to go through.

The first presentation is going to be on our continuing work which is based on a mandate to develop a unified payment system for post-acute care. We're going to do a couple of things. One is to examine the developing model in more detail, answer some questions that were raised at the last meeting, and then begin a discussion of some companion policies that are likely going to be needed as we develop this work, including looking at the potential for some regulatory changes.

So Carol and Dana are going to be leading us through this, and, Carol, you look like you're going to begin.

DR. CARTER: I am. The IMPACT Act of 2014 requires the Commission to evaluate the feasibility of a unified payment system for post-acute care. We have

discussed many times that even though the patients are treated in different settings and they can be similar, Medicare payments differ substantially. The Commission has noted that Medicare needs a more uniform approach to paying for post-acute care.

The IMPACT Act includes two opportunities for the Commission to weigh in on the design of the PAC payment system. In the first mandated report, due next June, the Congress is looking to MedPAC to recommend key features of a prospective payment system that is based on patient characteristics and not the site of care. It also asks that you consider the impacts of replacing the current PAC payment systems with a unified one. CMS will begin collecting common patient assessment information in October 2018. The Secretary's report is due in 2022 and must use two years of the common patient assessment information. A second MedPAC report requires the Commission to make recommendations and detail a prototype design. Assuming this timetable, this report would be due in June 2023.

Today's session is the second in a series of presentations on this topic. In September we presented our approach to the mandate. As required by the mandate, we

are using data from CMS' demonstration to develop a model to predict the cost of stays, and these predicted costs could be used to establish payments. Using that model, we will estimate impacts using a full year of PAC stays. Today, we wanted to come back and address some of the issues raised in September. In January, we will review our results of modeling all PAC stays in 2013 and our estimates of the likely impacts on payments.

The primary goal of the PAC PPS is to establish a common payment system that spans the four PAC settings -- SNFs, IRFs, home health agencies, and long-term-care hospitals -- with payments based on patient characteristics and not the site of service. But even with unified pricing, fee-for-service incentives will remain for PAC providers to minimize the care during a stay, to discharge patients quickly to another provider or setting, and these multiple PAC stays do not support care coordination. The Commission believes that Medicare needs to move away from fee-for-service payment and toward integrated payment approaches that put providers at risk for all health care spending and outcomes during a longer period of time, such as episode-based payments. Therefore, a unified PAC PPS

should not be considered the end point for payment reform but a good first step.

In September we reviewed our progress to date in designing a unified PPS. We developed a common unit of service, the stay, and a common risk adjustment method using the PAC-PRD data. The risk adjustment includes patient age, clinical conditions and comorbidities, functional and cognitive status, and other aspects of care, such as wound and ventilator care, and difficulty swallowing.

We are required to develop a PPS that spans the four PAC settings, but, currently, the home health benefit does not cover nontherapy ancillary services such as drugs. For our work, we assumed that the home health benefit would remain the same, so we developed one model to predict routine and therapy costs for the four PAC settings and a separate model to predict NTA costs across the three institutional PAC settings. The predicted cost would form the basis for a common payment. Based on patient characteristics, the models would establish one payment for routine and therapy services and a separate payment for NTA services.

We presented our preliminary results, looking at how well the models predicted the costs of stays. Both models are reasonably accurate and could be used to establish payments. We underscored that a unified PPS is likely to change how and where PAC services are furnished.

In September several issues were raised that we wanted to discuss today. Kate asked us to think about our approach to estimating costs and payments. Several of you mentioned additional patient groups to include in our analysis. Your discussion raised the point that even with an improved PPS, companion policies will be needed to dampen the incentives for fee-for-service. Alice asked about the outcomes of CMS' demonstration, and we'll review those. Kathy noted that CMS will need to monitor the implementation of the new payment system, and we included a discussion of that in the paper, and we'd be glad to discuss that on question. And Warner asked about providers having the flexibility to offer a range of PAC services and the need to waive some regulatory requirements to facilitate that.

So turning to the first issue, Kate asked us about how we were estimating costs and payments under a PAC

PPS. We can reasonably accurately predict the actual costs of stays, but that might only serve to replicate the current disparities in payments across settings. Ideally, we would want to predict the costs of efficient care in the most appropriate setting. Unfortunately, current practice patterns reflect a variety of factors that shape where beneficiaries get their care and how much they receive. The patterns do not necessarily reflect needed or efficient care. Further complicating the picture is the lack of evidence-based guidelines to help identify which beneficiaries need post-acute care, how much care they need, and where those services would be best provided. In sum, we know that the current practice patterns do not necessarily reflect efficient PAC use, but we don't know what the patterns of care should be.

We also need to proceed with caution in basing prices on the lowest-cost setting. The lowest-cost setting, home health care, may not be feasible for many patients, so basing payments on this setting for all conditions may not be appropriate.

Given the lack of clarity about the appropriate mix of PAC services, we have estimated the cost of care

using the current average mix of settings. This is a conservative approach because payments would be based on current utilization and would be least disruptive to providers and beneficiaries. However, over time, as with all prospective payment systems, payments would be recalibrated to reflect shifts in practice patterns that would change the average costs of care.

At the September meeting, several of you asked for preliminary results for additional patient groups. We have expanded the groups, and you can see them listed on the right-hand side. We added several clinical groups, two functional status groups, a group for the cognitively impaired, two groups for patient severity, and retained the community admitted, disabled, and dual-eligible groups. And the definitions of each of those are in your mailing materials.

The results for these more detailed patient groups reinforce our previous findings. For the model of routine and therapy services -- that's the one on the left -- we previously reported that over all stays, the ratio of the average predicted cost to the average actual stay cost was 1.0, and the model explained 56 percent of the

variation in costs across stays. For all of the new patient groups, the ratios of average predicted cost to average actual costs were 1.0 or close to it. Given the very large differences in costs between home health and institutional PAC settings, an adjustment will need to be made for those stays treated in home health care settings. Otherwise, these stays will be considerably overpaid, and the stays treated in institutional PAC settings would be underpaid.

On the right-hand side, you see the results of looking at the model combining routine, therapy, and nontherapy ancillary costs, and this would be with the home health stays excluded. The ratio of the average predicted cost to average actual costs across all stays was also 1.0, and the model explained 36 percent of the variation in costs across all the stays. The share of the variation in stay costs explained is lower because NTA costs are typically harder to predict than therapy costs and because this model excludes the home health indicator, and that makes it easier to predict the costs of stays. Across all the different patient groups, the ratios are 1.0 or close to it for most of the groups.

These preliminary results suggest that a unified PPS with a common unit of service and a common risk adjustment method is possible. The results also suggest that payments based on these predicted costs would not give providers strong incentives to select some types of patients over others. For example, the approach does not favor treating rehabilitation over medically complex patients. And we would expect the new payments to shift where patients are treated, both across and within settings.

MS. KELLEY: A unified PAC PPS will be a substantial improvement over the current siloed payment systems. Under a unified PAC PPS, Medicare will establish a common base price for patients needing post-acute care. Payments would vary based on patient characteristics, not on the site of service. Payments would be higher for sicker and more functionally dependent beneficiaries. Unlike in the current SNF and home health payment systems, providers will not be able to increase payments by increasing the amount of rehab they provide.

But, by itself, a unified PAC PPS would put providers at risk only for the care that's furnished during

the stay. Providers could reduce their costs by providing more efficient care, but they could also reduce their costs by stinting on care or by discharging patients earlier, which could compromise patient outcomes. They could discharge patients to other PAC providers, which would generate additional stays. At the same time, they could also increase revenues by admitting patients with marginal care needs. To counteract these incentives, policymakers will need to consider companion policies to a unified PAC PPS.

This slide outlines some companion policies that might be considered.

First, value-based purchasing could be used to tie a portion of payments to quality. Providers would then have an incentive to furnish the care needed to achieve good outcomes. CMS could also tie a portion of payment to resource use over the course of an episode, with a measure of Medicare spending per beneficiary. Providers would then have an incentive to ensure efficient care over the course of the PAC episode, not just during the time the patient was under the provider's care. I'll talk more about how an MSPB could work in a moment.

Another companion policy to consider is a readmission policy for all PAC settings. This would align hospital and PAC provider incentives to furnish adequate care within the PAC stay and to ensure safe transitions between settings.

Others have raised the possibility of contracting with a third-party vendor to manage PAC services. The vendor would be responsible for the costs of PAC services in a given area. Because the vendor would be at risk for the care within the area for a defined period of time, it would have a financial incentive to encourage beneficiaries to select the lowest-cost appropriate setting for beneficiaries needing PAC.

It would also be important for CMS to track provider responses to the new PAC PPS, such as changes in utilization and lengths of stay, and outcome measures such as readmission rates, emergency room visits, and changes in patient function during the PAC stay.

Finally, it will be important to include in the new PPS elements that protect providers, such as high-cost outlier payments. A transition period will also be necessary to give providers time to adapt to the new

payment environment. We will talk more about those policies in January.

This slide shows how a Medicare spending per beneficiary measure could be used to hold providers responsible for resource use during the course of an entire episode of care. As you know, an MSPB measure is currently used for hospital payment. As shown in the first row, the hospital MSPB includes all Part A and B spending during the hospital stay plus the 30 days after discharge. As with the hospital measure, a PAC MSPB could begin with an admission to the PAC setting and continue for 30 days after discharge from PAC. This is shown in the second row. PAC providers would also have an incentive to make judicious referrals to subsequent PAC care. A PAC MSPB would more closely align hospital and PAC providers since PAC providers would be at financial risk for their own episode spending. The IMPACT Act does require the Secretary to develop a resource use measure as one of the common quality measures across PAC settings.

I mentioned the importance of monitoring the effect of a unified PAC PPS on patient outs. In September Alice brought up this issue and asked what we knew about

how outcomes vary across PAC settings currently. To date, the PAC-PRD is the only study that has used comparable patient assessment data to examine patient outcomes across a wide range of conditions treated in the four PAC settings, and we have briefly summarized the findings on this slide.

The PAC-PRD evaluation looked at risk-adjusted 30-day all-cause readmission rates and two measures of function: changes in mobility and changes in self-care. The study found no statistically significant differences in the risk-adjusted readmissions rates of SNFs, IRFs, and home health agencies. LTCHs did have lower readmission rates for all conditions combined and individually for respiratory conditions and circulatory conditions. These lower readmission rates might be expected due to LTCHs' ability to offer hospital-level care.

The PAC-PRD evaluation also looked at mobility improvements and found no significant differences across the PAC settings. As for self-care, across all patients, improvements were similar for patients treated in SNFs and LTCHs, but were significantly better for patients treated in IRFs and home health agencies.

Policymakers will also need to consider changes to the regulatory requirements for PAC providers. As you know, Medicare has very different requirements for the different PAC settings, with more stringent requirements for LTCHs and IRFs. A unified PAC PPS would necessitate moving away from setting-specific regulations. Otherwise, providers in different settings would be paid the same for treating the same patient even though they would incur different costs associated with their differing regulatory requirements.

In the short term, policymakers could level the playing field by relieving IRFs and LTCHs of certain regulatory requirements governing patient care. For example, IRFs might be relieved of the general requirements for intensive therapy, and the required frequency of physician visits could be reduced. The IRF 60-percent rule and the 25-day length of stay requirement for LTCHs could also be reconsidered.

In the longer term, CMS could consider developing a common set of regulatory requirements for PAC providers to ensure a baseline level of competency while still allowing providers the flexibility to adjust their mix of

services and staffing to meet the needs of patients. Policymakers could also consider changes to the Medicare benefit that would standardize covered services across PAC settings.

This slide outlines the domains that might be considered for a common set of regulatory requirements. Possible domains include staffing levels and mix, the availability of physicians, and the frequency and content of patient assessments and care plans, as well as other domains listed on the left-hand side of the slide.

As noted on the right-hand side, one should not necessarily assume that standardizing regulatory requirements across PAC providers would result in the application of current SNF regulations to all institutional providers. A common set of requirements might actually raise the staffing and physician oversight requirements for SNFs. CMS could also develop specific requirements for providers who admit patients with particular care needs, such as wounds or ventilator care. For example, PAC providers that admit patients who require prolonged ventilator care could be required to have sufficiently trained staff and equipment to furnish appropriate nursing

care and respiratory therapy and to demonstrate use of evidence-based ventilator weaning practices.

In summary, our work thus far has shown that it will be possible to design a reasonably accurate unified PAC PPS using a common unit of service and a common risk adjustment method. Payments based on these models would give providers little incentive to selectively admit or avoid certain types of patients, and payments would be reasonably accurate.

Ideally, the unified PAC PPS would make payments based on the resources needed to efficiently provide high-quality care in the most appropriate setting. But as Carol discussed, we lack information about which settings represent the best value for the program for many beneficiary conditions. So we propose to pursue a conservative strategy at this time: to base payments on the current mix of settings and costs. This strategy means that initial payments under the new PAC PPS would reflect any current inefficiencies. But over time, as practice patterns change, Medicare will update its rates to reflect changes in the costs of care and shifts in where beneficiaries receive their care.

Although a common PPS for PAC stays would begin to rationalize Medicare's payments, it would not correct the underlying incentives in fee-for-service payment to furnish unnecessary care or to provide low-quality care if it is less costly. Short of broader reforms that establish payments for larger bundles of care or population-based payments, Medicare would need to adopt companion policies to deter undesirable provider responses to fee-for-service. In addition, Medicare would also need to consider moving away from setting-specific regulations that impose differential, setting-specific costs. And, of course, it will be important for CMS to continually monitor provider behavior and beneficiaries' access to quality post-acute care.

That concludes our presentation. We've noted a few possible topics for discussion here on this slide, and we're happy to take any questions.

DR. CROSSON: Okay. Thank you very much, Carol and Dana. We're going to go to clarifying questions, and I'd like to start with one on page 11, if I could.

Just listening to your closing remarks about going beyond this policy and where CMS might want to go

eventually, I wonder if you could elaborate on this third party managing the post-acute care idea because I could think of a couple of ways that this could take place, and maybe it actually it is being done, so I don't know. But one would be paying a third party to manage, and there would be an administrative fee, and that fee, all or in part, would be at risk based on the quality and cost. But Medicare would still be paying fee-for-service to the providers.

Another way would be something like a global payment, either per beneficiary or in the population and area or something, where essentially, much like Medicare Advantage, the entire payment per whatever would go to the entity who would then manage that much in the way that Medicare Advantage plan manages general Medicare services.

So are both of those ideas contained in this bullet point or what?

MS. KELLEY: Yes. I think both of those ideas are contained in that bullet point, and I think both of those ideas are in use in certain markets in the country.

I think Carol and Evan spoke last year about interviews they did.

DR. CARTER: Yeah. So, last year, Evan and I talked to many, both systems and MA plans, and we did talk to three or four different benefit managers, where somebody is paying -- in this case, it was MA plans -- were paying a fee to basically manage the care, but fee-for-service was running underneath that. In the MA world, sort of they were paying -- they were not paying their providers directly. But my understanding is that there are sort of sub-capitation arrangements also.

They predict the expected -- using -- many of them go into actual hospitals while the patients are still in their stay and start to assess the patient as to kind of their characteristics, their functional care needs, and using kind of a large database, compare those patients to other patients in their database to predict where would be the best setting for the patient and the expected length of stay and the expected functional change one could expect for the patient with those characteristics. I mean, I think that kind of predictive modeling is pretty common for these benefit managers.

So I think we're thinking either one of those arrangements might work, and I think both are currently in

practice.

DR. CROSSON: Thank you so much.

Clarifying questions? Mary.

DR. NAYLOR: Can you clarify? I don't know. This is clarifying, so I'll ask. Value-based purchasing and the readmission policies, do you think that they are sufficient to really promote the care coordination and care management that is essential for people at this phase in their journey?

DR. CARTER: Maybe.

[Laughter.]

DR. CARTER: I guess one thought I have is it's hard to -- I mean, we had these global measures of whether those are effective. Like readmissions is a rather -- you know, it's a blunt instrument. There are lots of things that can go wrong with a patient before they're actually readmitted, but that is one sort of endpoint of a progression you would hope patients don't have, so poor hand-offs might result in readmission rates. But you could imagine poor care not being picked up in a readmission rate.

I think an MSPB measure starts to look at

coordinated care and how safe and good are those transitions, and some of the car coordination quality measures tend to be process measures. So I guess I'm trying to think of a good outcome measure.

DR. NAYLOR: Maybe another way to say it is there's nothing that prevents us from considering, in the companion policies, explicit levers to promote care coordination.

DR. CARTER: No. And that would be a great thing for you all to talk about.

DR. NAYLOR: And the second is on the transfer policy. You addressed that very well. This was a great paper, addressed it very well in the paper, but I'm wondering if you could explain what -- you're trying, on the one hand, to prevent premature discharge, et cetera. On the other hand, you want to have some kind of regulatory relief to enable people to move when they're ready, if it's in three days or four days, to a lower, less-intensive site of care, if that's the best match.

So I'm trying to figure out, how do you navigate, thread that needle?

MS. KELLEY: So the current transfer policies

that are in place in Medicare now, for example, in the IRF PPS, for cases that are discharged from the IRF and then admission on the same day to another IRF, a SNF, an LTCH, or an acute care hospital, and the length of stay for that first IRF stay is shorter than average.

The first IRF is paid on a per-diem basis up to the full rate for the case, and so that, I think, helps allow IRFs to discharge early if they need to, but also protects the program from making excessive payments for patients that are discharged earlier than they might be and then readmitted somewhere else.

I'm not sure if that answers your question.

DR. CROSSON: Clarifying questions. I saw Cori, Jack, Alice, Kathy, David.

MS. UCCELLO: So, on this measure of resource use, can you remind me? Is this trying to highlight or flag when there's too much used or not enough?

DR. CARTER: I think that's -- I'm sensing in there a good point in the sense that we tend to focus on overuse, and that measure, I think typically looks at identifying high use. But you might use it as a measure of underuse as well, because if you saw that spending was sort

of not for a specific case -- I mean, I think these are always averages, but if a facility -- because these would be facility-level measures. If you saw a facility-level cost was always low, I think you really would then.

I guess the other thing I should say about MSPB packets, I don't think it's a measure that you should use in isolation. I mean, I think you need to look at the quality measures for exactly that reason.

DR. CROSSON: Jack.

DR. HOADLEY: So I was thinking about the same third-party vendor thing that Jay raised and wondering if in the experience that you've seen -- and maybe in those interviews -- were there issues of where the vendor who was doing this kind of planning or whatever the right noun is there -- I mean, I worry about a situation where they'd be co-owned by one of the types of providers, and you'd end up with conflict of interest. Does that come up at all in these situations?

DR. CARTER: It hasn't. We heard mostly positive things in that the beneficiaries, I think, liked -- we didn't talk to beneficiaries, but what people told us was there's so much confusion during the hospital stay about

where patients should go that actually having somebody guide that decision-making is helpful.

Also, if the network has already screened PAC providers to include -- and that's an "if" -- to include high-quality providers, then you're actually being guided to a place that provides good care, and so that could be good.

In at least one of the cases that I'm remembering, beneficiaries had the option of opting -- not taking the recommendation, and so that would be something to talk about, is whether in something like that, do you have to go with the recommended site? And I think some beneficiaries didn't -- were reported that they weren't -- they didn't like having a third person, so I think that that can go both ways. You are adding another layer, and that may be good, and in some cases maybe not.

DR. MILLER: Also, don't I recall in some of those discussions -- and this is a little hazy for me, and I'm moving off of the beneficiary discussion and talking more about the vendor and the providers.

There wasn't always open doors, so a vendor might be saying, "We want to manage," and some hospitals were

okay with that, some hospitals not okay with that. And I don't know that it was directly because of ownership issues, but there were some dynamics of who was who, what competition was occurring in the market that I also think played into some of this.

DR. CROSSON: And in some of those circumstances, could the hospital in fact be in a financial relationship with certain PAC providers?

DR. CARTER: Sure. I don't know that they were in the places where we were talking, but, I mean, lots of hospitals own home health agencies, and hospital-based SNFs are pretty few. But I think hospitals do have a financial relationship with PAC providers, yeah.

DR. HOADLEY: Yeah. No, it seems like there would be a number of things you would want to worry about. I mean, obviously, there's a lot of potential ownerships and conflicts, but overall, it sounds like it could be a substantial service to the beneficiaries involved.

DR. MILLER: So I'll just say this, and maybe you guys can talk about it at some other point in time, because this is clarifying. But, I mean, if this path were pursued by you guys, I mean, there would -- I mean, I think we

would be thinking there would be some designation from the Secretary that says this is who the third party is, and so the notion of what their interests are, as you said, would be worked through before.

DR. CROSSON: All right.

DR. MILLER: Sorry. Go ahead.

DR. CROSSON: Alice.

DR. COOMBS: On page 11 in the reading material, you talk about the HCC, and then there's a reference to the severity of illness indicator. And I was wondering how well that -- because you can have systems with -- you have five systems, five systems that are kind of mildly impacted versus three systems that are severely impacted.

I was wondering how well are we able to predict resource utilization at the level of the PAC. Are we able to -- because the ACC doesn't really tell you about the resources necessary that would be needed. It's a correlate in terms of risk adjustment, but for the immediate phase of the PAC, how much does that correlate with the amount of resources that -- like, for instance, you did a great job talking about the wound vac and events, but I'm wondering how well, if you were to look at those numbers and say,

"Okay. I can predict how much resources would be correlated with this number or that number."

DR. CARTER: So we did look at -- I'm not sure I'm getting your question, but we did look --

DR. MILLER: Can I ask? So what I'm not following, Alice, is we put up some model results that talk about the overall and then by category of patient, and then you seem to be asking the precision of the model in a different circumstances. I'm not quite following --

DR. COOMBS: So, if I came up with the severity of illness index that said it was a -- and you gave an example in the paper of a level 4, what kind of resource utilization would you project with that kind of level as opposed to a level 3, a level 2? Can you correlate that?

DR. CARTER: So what I'm reporting is for how well did the model predict cost for level 4 patients. That's the measure, and so you can see that the model did pretty well.

We haven't compared it to other levels of severity, so I don't know, and we could do that. But what we had heard from the conversation was we wanted to know how the model was working for very sick patients. So we

picked level 4 as an indicator of very sick patients, just like we also picked, oh, patients who have five or more comorbidities and sort of involving those -- and so those are the model results.

We didn't look at are the models more accurate if the patient is in an LTCH. This was sort of across all stays. Does that help?

DR. COOMBS: So that helps, but what I'm looking at is if I were an LTCH or a SNF or IRF is how much do I have to pour into that patient who rolls into the door. Am I able to say that this patient is going to be a consumer of a lot of resources? For the example of the wound vac patient, they may have severity of illnesses relatively mild, but they have an open wound that requires a lot of attention every single day. And so that patient is actually more labor intensive than someone who is coming for cognitive kind of --

DR. CARTER: Right. But what you can see from these results is those patients are more expensive, and their payments would be higher. And the payments match pretty closely with those costs. So, yes, you're right. The resources are higher, and so would the payments.

DR. CROSSON: Kate?

DR. BAICKER: So, just to clarify the clarification, my understanding from all this is that when you look at the predicted versus the actual, the model does very well, and those were those predicted versus actual ranges that we were seeing that were really very narrow, which suggest the model is doing a pretty good job.

There is a more subtle question embedded in what you're asking, which is can the providers do an even better job than the model, and can they then say, "Actually, the model is predicting this, but I know that this flavor of patient is on the high side, and this flavor of patient is on the low side."

DR. COOMBS: Right.

DR. BAICKER: If they've got a better risk adjustment model in mind than we do, they could do some selecting. On the other hand, it seems like this is soaking up a huge amount. Not only is the actual versus the predicted very close, but it's soaking up a huge amount of the variation. There's not a lot of R-squared left to go around. So, even though that seems like a real potential risk, it doesn't look like in practice it would

be all that big, but time would tell.

DR. COOMBS: Right.

MS. KELLEY: And to build on that point, I mean, this is a small sample, so there's only so finely we can slice it, but that's another reason why we looked at severity in a couple of different ways, to try and see how it worked when you described it, a ventilator patient versus a wound patient versus a severity of illness floor. We tried to get at it in several different ways.

DR. MILLER: And you're going to come back and look at it again using the full-claim set, just to get another view on it to see how accurate the models are and in a sense try and triangulate.

MS. KELLEY: Right. And that would allow us to make some of those finer cuts.

DR. MILLER: Exactly.

DR. COOMBS: Not to slip into Round 2, but decisions may be made by facilities based on that information, so that there may be a predilection for certain facilities to take certain types of patients, obviously because they have familiarity with the resource utilization.

MS. KELLEY: And I think that that's not something we would want to discourage, right? I mean, for certain types of patients, you really do want expertise.

DR. CROSSON: Kathy.

MS. BUTO: My questions really go to the differences in coverage and mainly for home health patients and SNF patients with the three-day hospital stay requirement and the homebound requirements for home health patients and so on. And I recognize that the model does a really good job of picking up the differences in the severity of patients and so on.

I guess I'm wondering -- because as I think about the eventual goal here, that we're trying both to neutralize or we don't want payment to drive the site of care, on the one hand, for patients who are similarly situated and could be in a number of different settings, and I guess we're also trying to reduce the likelihood of inappropriately high cost, say in rehab and other areas. But how do the nature -- how does the nature of coverage, sort of the entry criteria for the patients -- does that have any impact on -- or any relationship to how good the model is going to be and actually providing payment in

certain settings? And I guess I am particularly thinking of home health because it seems to me there, we might have a very different institutional situation, since there isn't an institution. So you have different costs and so on.

So maybe you could address that, and I think you did address some of the institutional requirements that might need to be relaxed or changes, but now I'm wondering is there any justification -- but maybe this is Round 2 -- of having all these different kinds of institutional settings.

So, really, it's question one about the coverage and how the different nature of the patients entering into these different settings has any impact or has been considered in the model.

DR. CARTER: So the model reflects current practice, and we know that coverage rules do influence clearly where patients go. The IRF requirements for intensive therapy mean, if a patient can't tolerate intensive therapy, which is often interpreted as three hours of therapy, those patients don't go to IRFs. And so we would be predicting cost of patients in IRFs for the patients that could tolerate three hours of therapy.

That's kind of built into the model in the same way that for patients who don't have a qualifying SNF stay, they may go to other settings. And we've heard that sometimes those patients end up in IRFs because they don't have a qualifying hospital stay, and that's not a requirement for IRFs, or they can go home -- if they can go home, you would pick those -- the cost of those patients up in the patients that we're trying to predict that we're seeing in home health.

I don't think that right now our -- the model doesn't try to influence in any way setting use.

MS. BUTO: Where they go.

DR. CARTER: Where they go. But that is embedded in the current utilization practice patterns.

DR. CROSSON: Okay. Bill and then David.

MR. GRADISON: I'm looking at page 23 in the mailing. My understanding is that this model creates the possibility that there might be two different regulatory standards supplying to a single -- the same provider. I'm not sure I got that, but I think that's how it would work, and I'm trying to think about any analogy that would help me understand this.

I suppose a rural hospital that has swing beds has two standards, one for the hospital patients and one for the nursing home patients, and so maybe that would be the same idea here, that you might have two different -- maybe more than two standards, depending on patient group A, B, and C. Do I get it correctly?

MS. KELLEY: Yeah, that is exactly what we were thinking of, and I think your notion about the swing beds being an example of where that currently happens is a good one.

MR. GRADISON: Thank you.

DR. MILLER: So you might have some minimum -- and this is an evolution. This is not happening today or this week. So, you know, you might have some minimum regulatory requirements and then say if you want to take certain types of patients, then you have to have these additional requirements. So if you want to take vent patients, you need to be able to do these things. And I think in some ways some parts of the industry are kind of evolving in that --

MS. KELLEY: Well, yes, and I should let the SNF experts speak about this, but the recent staffing changes

that CMS has been considering have been focusing -- for SNFs, have been focusing on having facilities adjust to the patient mixes that they serve.

DR. NERENZ: Can you just remind us what the cost data are here, actual costs?

DR. CARTER: Yes. So the simple version is we took charges off the claims and converted them to cost using facility-level, department-specific cost-to-charge ratios. There's a few twists because we don't have nursing level on the claims. It's a broad, you know, room rate. So we use the PAC-PRD data that had resource use for nursing and constructed an intensity index, if you will, of the nursing component and applied that to a daily rate for the nursing, to adjust it up and down for the resource for nursing.

DR. NERENZ: Okay. So answer this as a Phase 2, if you want. I'm just curious in going with this question how different this methodology is from, say, the DRG development where it was essentially time-motion analysis. I'm not sure if people quite say it with stopwatches, but having been involved in some of the long-term psych development, it was basically built on time-motion studies,

and then actual time to --

DR. MILLER: I don't think that's right. I don't think it was time-motion.

DR. NERENZ: Well, I did for long-term psych, and it was.

DR. CARTER: The RUG system is more like that.

DR. NERENZ: RUG, well, RUGS is like --

DR. CARTER: The RUGs was -- yeah.

DR. MILLER: You said --

DR. NERENZ: Well, no, I sort of threw them all together, but I --

DR. CARTER: They're different. Yeah, the DRGs didn't do that.

DR. NERENZ: Okay. And I just was speculating, and that can be Phase 2, if it would have mattered. Probably doesn't.

Okay. Then the second clarifying question, and we could look at Slide 9. Again, probably a reminder, we probably saw this in September. You could get these statistics by predicting really small differences around the overall average by group, or you could get these statistics by picking up really big marked differences. So

just can you give us an idea, let's say, for the ten clinical groups, what's kind of the ratio from most expensive to least expensive? How big are those differences?

DR. CARTER: So the clinical groups vary, so some of them are expensive and some of them are less expensive. We have ratios for -- well, you can see in the paper, you know, you have ratios for each of the groups.

DR. NERENZ: [off microphone].

DR. CARTER: Yeah, yeah. So in the -- this is just summarizing what's in the paper. So there's an actual row for each of the ten conditions, and I didn't include the average cost of the groups, but we could do that. So the -- does that answer your question? I'm not sure...

DR. NERENZ: I have a table on page 12 [off microphone].

DR. CROSSON: David, microphone.

DR. CARTER: So on page 12, you see each of the ten clinical conditions and the ratios for each of them.

DR. NERENZ: But that's the accuracy. I'm interested in, like, is ventilator care five times as much as, like --

DR. CARTER: Yes. And we can get you that information. I just didn't --

DR. NERENZ: Okay, no, I just --

DR. CARTER: They vary a lot.

DR. NERENZ: Are these groupings picking up really big marked differences, or are they picking up "scooches"?

[Laughter.]

DR. CARTER: So the groups are broadly defined, in part because the sample size is pretty small. In fact, there were some groups I was particularly interested, but I thought they were too small to report. And Alice had asked about, you know, medically complex with, I forget what it was, dialysis, vent, and something else. And there weren't the cases to have a stable estimate, so I didn't report that. But we'll come back to that one when we have a bigger sample size.

So we were trying to balance sort of how big was the group with also retaining some clinical coherence.

DR. CROSSON: Okay. I think we're ready to move on to the general discussion. Alice is going to lead off. I'm just warning you in case you didn't remember. But I

would like -- and, Alice, you can lead off in any way would like, but I think just in terms of the discussion, what I'd like to do is have a first round on the model itself. Further discussion about the model, recommendations to change the model, whatever additional information. And then a second round on the companion policies, managing the utilization and cost, quality, and the issue of the regulatory piece. And we'll do all those together. Okay?

DR. COOMBS: Nice job. Really nice job. And I'm very interested in this stuff because I'm in the ICU, and I think it's really important because the placement of patients from the ICU can be impacted greatly by the number of beds and the accessibility to those beds.

So, first of all, I think to speak specifically about the model, I think the model works. I was just a little bit concerned that it reflect the resources utilized, and I think we're at the place where it actually does.

The question I have long term is what does it do to the industry, how does it move the industry to kind of do things that are innovative versus things that restrict their capacity. And restricting their capacity might mean

that they take on a totally different personality, which they might restrict the kind of aggressive interventions that they may have had.

Once that happens, the state regulatory impact becomes important because there's some states that have rules and regulations whereby if you lose this, you have to have a bigger climb to get back to where you were. And I'll jump to the last thing, which is the butting of heads between federal and state may be significant in some areas where you may need to have -- Bill was speaking about something that I was thinking about at 5 o'clock this morning, which was how can you take on different personalities to accommodate all the things that a PAC has to deal with.

For instance, you talked about the notion of how do we relax certain regulations, but then you have the state regulations. So for Massachusetts, there are certain state regulations about if you're going to operate in this realm, you're going to have to do this. So is it possible to have, you know, five different children under the same parent, you know, if it were necessary?

So I think that this whole business of how do you

address all of the regulatory changes that are down the pike, the state, the federal, and then the companion policies that we decide to implement.

Back to the companion, which I think is definitely the spouse of this whole thing, it has to be in operation, because what I've seen as an ICU doctor is that patients will go to an LTCH and there will be this churning that occurs in the community, and there's really no consequences. And I've always asked if a patient goes to one facility and they go home and then they bounce back to another facility, an IRF or whatever, how is the cost attributed across those two spectrums right now? And I'm not sure that, you know, we have a good containment of how that is actually done. Maybe you guys can speak to that, but in my neighborhood, I'm not sure that there's any denial of the second or the first or how it works.

MS. KELLEY: There are certain rules. There's an interrupted-stay policy for LTCH care. For example, if a patient leaves the LTCH and goes to a SNF and then comes back to the LTCH within some period of time, there are payment consequences for that for the LTCH.

You know, I think those are the types -- there

are additional types of companion policies that we would want to think about in terms of discouraging certain kinds of behavior. I'm not sure if that answers --

DR. MILLER: Yeah, I mean, I think the discussion around things like the spending -- I think we're saying MSPB, but basically the spending over some period of time, whether it's 30 or 60 days, gets at some of this. You used the word, I think, "churning" in your comments, and so if somebody's kind of balancing patients, and let's just agree for a moment, inappropriately, then that metric would begin to light up if that was happening.

To what Mary was saying, and you were responding to, of course, you want a companion with that, that it's not just about spending, it's also about outcomes, like readmissions or functional status or what the case may be, or what I suspect Mary is going to be reaching for, other measures that kind of force a level of coordination to occur, you know, recognizing that we still have something of a fractured system here. So I think this report and some of their ideas and I suspect some of the things that are going to get said here will speak directly to those kinds of concerns.

DR. COOMBS: So the last thing I wanted to speak about is the whole notion of a vendor or someone to help -- a navigator, I will call it, for all intents and purposes. What I found also is that some patients who say they have a procedure at this facility and then they go to an IRF or SNF or LTCH that's geographically very far from their primary -- where they receive their primary care, and so that when they bounce back, they bounce back to another acute-care hospital.

Now, it jibes with the whole thing of coordination of care, but also it's very problematic in the sense that these new providers quality-wise don't understand fully about what happened at the institution. And in my area, I can say that nearly 90 percent of the time when that happens, when they bounce from acute-care facility, IRF, or LTCH, and then to my facility, and we call to get that patient transferred back to the acute-care facility, they never have beds in 90 percent of the time. So then you have -- it's this truncated care that occurs.

So I think the vendors would be very important in the sense that they might be able to geographically work with the systems to make sure that patients are in close

proximity to where they receive most of their care. So I think, you know, as I think about it, we've had some really unfortunate patients that, you know, they get in this treadmill and they wind up so far away from where they received their original care, and there's a duplication of lots of services, and care coordination is at its worse.

Thank you so much.

DR. CROSSON: Yes. Kate, did you want to make a comment on this? Oh, no? Okay. So I just -- Alice did bring up one thing about the interplay between federal and state regulation. Did you want to make a comment on that?

MS. KELLEY: There will be some interplay.

DR. CROSSON: Okay.

[Laughter.]

DR. CROSSON: Check.

MS. KELLEY: It's definitely something I think we'll need to be cognizant of, but I don't know that we can take on a 50-state analysis of how this would work. But it definitely will, I think, vary from state to state.

DR. COOMBS: I just think that [off microphone] we need to have some kind of strategy for which institutions might be able to -- not wiggle room, but to

work within the confines of what they have to deal with.

DR. MILLER: And, I mean, we had a little bit of this conversation yesterday. Some of this goes on now. I mean, Medicare generally sets its policies by saying, you know, this is what we do, we have conditions of participation, whatever the case may be. But if a state determines, say, for example, you know, what PA or an MP can do or a facility can do generally, Medicare sort of says, all right, well, in that state that's the way it's going to be. I think the real question will be whether we're trying to rebuild that at the state level, which I'm with you guys, I think that would be a very hard undertaking, or we're just going to continue to kind of accept the licensing requirements of the states and then Medicare kind of overlays that.

MS. KELLEY: And I think that, you know, those different state environments will absolutely affect how things play out under the new PPS in terms of, you know, right now New York has no LTCHs, the states doesn't really allow them. Other states have plenty of them.

And so what will happen under a new PPS will be very different, I suspect, in Arkansas than it is in New

York based on the providers that are available.

DR. MILLER: That's what I was trying to say.

DR. CROSSON: And so it probably will be useful down the line to at least identify some of those major issues, you know, like, you know, we talked about telemedicine yesterday, and, you know, it's a great idea except that, in fact, in some states, many states, you can't do it across state lines. So to the extent that there are, you know, not all but major state issues that impact our thinking, that would be useful down the line.

DR. COOMBS: I just want to say one other thing. You can also look at nursing ratios that are state regulatory versus --

DR. CARTER: Yeah, I was thinking about that in the nursing home context.

DR. CROSSON: Okay. So the first round on the model, Kate?

DR. BAICKER: So I really appreciated the deeper dive into understanding how the model works and the potential for setting an efficient threshold versus the patterns that people are actually utilizing right now, and where you've landed makes a lot of sense to me in terms of

the limited data that's available right now. And the longer-term vision of going to one schedule that's calibrated to the right site of care for the patient rather than where the patient is going under the current system seems like where we want to get. But we can't quite get there yet, and this seems like a really productive step in that direction to me. I think all the supportive policies would make this model work even better in terms of loosening the restrictions that are differential across sites. Collecting the new data that's going to be collected between now and the next report will let us figure out what the most efficient site would be ideally under those level playing field requirements.

DR. CROSSON: On the model.

MS. BUTO: Yeah, the one thing that -- and I don't know if it's strictly on the model because it's really in the section of the paper that talks about the work from the PAC demo on outcomes, is that there are, there appear to be some different outcomes in different settings. So I guess one thing I would say -- and I notice we do recommend or suggest that a robust evaluation has to go on and so on as more data become available. But I think

it's important for us to track whether those changes continue or those differences continue under a model or whether they actually smooth out so we begin to see more uniformity, because I think ultimately in the paper we get to -- you know, when we get to the regulatory requirements part, we suggest, well, maybe we really need to sort of make those more uniform. But I'd be interested to know whether these outcomes, which in some cases are different currently, continue or not, because there might be patient differences or intensity of care differences that matter that we would want to preserve as we go forward with the model.

So that's the only thing about the model.

DR. CROSSON: Okay. I think we're ready to move on. It sounds like we've got a level of comfort with the model as it is so far, so let's -- David?

DR. NERENZ: Just one very quick question, and this is a technical detail. In looking at how the model would be implemented, presumably if it functions like a DRG sort of model, a patient would be in A group -- not in A group?

DR. CARTER: For sure. We have not developed the

classification system. Right now we've looked at groupings of patients.

DR. NERENZ: Yes.

DR. CARTER: These could be the classifications.

DR. NERENZ: Okay. I'm just trying to figure out -- let's say you just did a straight multiply classification, you've got 10 conditions, you've got five severities or functional levels, you've got three -- if you just totally combine them all together, it's 150 groups, which might be fine. I'm just curious where that next step is as you envision it.

DR. CARTER: We haven't -- and certainly for this report we will not develop what you're talking about, which is a classification system. And those because of their clinical coherence -- I mean, I think it's really implement for a classification system to be clinically coherent so that you have for each case mix group not a lot of variation. I do not know that that would really be in our wheelhouse.

DR. NERENZ: Okay.

DR. CARTER: So something like this would inform a classification system, but I don't -- certainly for this

report we would not be developing a classification system.

DR. NERENZ: Okay. That's fine. And I just wanted that sense, and that's fine.

DR. MILLER: And as you know, this might be something where CMS goes through the data, gets kind of lumpy categories, then sits down with clinicians and starts to get it right.

DR. CARTER: And I should say, I mean, there are PPS's, like the psych PPS isn't a strict -- you know, there's not a DRG. It's a regression model kind of payment system. So you wouldn't have to wait for a classification system to move forward because we have a PPS in place that is more like this. For each factor that applies to that patient, payments go up or down.

DR. CROSSON: Okay. Good. So we have on the table, if I've got it correctly -- we've got kind of three bodies of companion policies. One has to do with managing costs and utilization, dampening fee-for-service incentives, including the notion of a post-acute care manager of some sort. We have issues with respect to how to monitor and potentially improve the quality of care over time, and then we have the issue of the regulatory

environment. So, rather than divide those, I'd like to take them all together and ask Commissioners if, as we go forward with this, we definitely want to look more deeply at X, Y, or Z.

Bill, and then we'll come up this way.

MR. GRADISON: With regard to the possible role of a third-party manager, I would hope that, as you move forward, you explore the possibility that we may actually want to create an environment where a new kind of insurance mechanism got built up there that really may not even exist today that would go at risk, and let me explain why in just a sentence or two.

I'm increasingly concerned about the financial burden of it as being put on hospitals in the sense that they are being dinged, if you will, for readmissions and potentially other things, and they're probably the first suspect when we talk about this. Maybe the hospital, because it is post-acute care, should be at risk with regard to the expenses that happen further down the line.

I think that's a dangerous road. Many hospitals are not all that well financed to start with, and they're certainly not very well-equipped on average -- I know there

are exceptions -- to be insurers. Furthermore, the hospitals -- and we have talked about this in other contexts -- have been busily engaged in building up their fixed cost by hiring a lot of positions.

So I just would be -- I'm not pushing that that should be the only option, but I do wonder whether we're creating a situation whether private capital might come in -- it might be existing insurers or somebody new -- that might be willing to take this risk on so that the third-party manager wouldn't just be managing. They would also be insuring.

I hope you explore that thought a bit. Thank you.

DR. CROSSON: Let me see hands, how many people we've got. Yeah. So let's continue this way. Craig? Did I miss anybody? And then we'll come down here. Craig?

DR. SAMITT: Yeah. I guess I would jump in and say that I disagree with Bill. I mean, I think we add a layer of complexity if, yet again, we're going to create another accountable party, a third party who's going to manage the post-acute care risk when -- isn't that the intent of what we're trying to accomplish, either through

ACOs or even the discussion we had yesterday about per-beneficiary payment for primary care? Those are the exact positions that are very well positioned to look at utilization, whether it's preadmission, inpatient, or post-acute. A high-performing clinical practice should be responsible for post-acute care as well.

So I'm not comfortable with the notion of the creation of yet another layer when I don't think we've given enough opportunity to see that the layers that currently exist, when held accountable, can manage this cost and utilization well.

DR. CROSSON: But, Craig, you do generally agree with the notion of rather than paying one PAC provider at a time, that some entity managing that prospectively makes sense?

DR. SAMITT: Yeah. And you talked at the beginning that we're still basing these reimbursements on a fee-for-service chassis, and if we could shift more to a bundle, that would be much more effective. I would absolutely endorse that. I just think that we create a -- when we say pay a third party, are we thinking yet a different third party than all the parties that exist

today? I think we should pay a third party that is already an existing entity and just amp up the accountability.

DR. CROSSON: And so I'm not sure I see a vast difference between what the two of you are saying. Some of this is just language.

So, when Bill says insurance risk or insurance entity, as you're talking about carrying risk and managing, you're really talking about something like that.

DR. SAMITT: Except I think that a health system can be the accountable party. It doesn't have to be yet another insurance function.

DR. CROSSON: Another insurance company.

DR. SAMITT: Right, exactly.

DR. CROSSON: Okay. All right. Good.

Sorry. Rita.

DR. REDBERG: Well, I can say Craig said a lot of really what I was going to say. I have a lot of concern about adding yet another third party. There are a lot of third parties, as Craig said, already in the mix, and I don't think another one is going to add value.

And I sort of like to think of it, maybe as Bill said, with the swing bed. I mean, I think we're talking

about site neutral and doing what's best for the payment, and we heard a lot of work that showed all of the different facilities don't really -- it's very hard to differentiate the patients that go to them and the outcomes that come from them. And I think that's what we need to be concentrating on, is that making sure our beneficiaries are getting the right level of care. But I don't think they're getting it by having different kinds of payment for all these different facilities, and that's simplifying it in sort of a bundled payment.

And I think if we're tracking outcomes and making sure that outcomes are high quality, that's the best way to ensure that we're not getting too much and not getting too little service because -- and that's what we want, I think, is to pay for and get the best outcomes for what we're paying for, which is not what we're doing now.

DR. CROSSON: Okay. I'm sorry. Sue, I didn't see your hand.

MS. THOMPSON: Well, Craig and Rita have actually said much of what I wanted to say, but in the context -- and while anecdotal -- of our Pioneer ACO, this work just really resonated, and I think there's a lot to be learned

around waving the three-day regulation for three-midnight rule, the homebound criteria qualifying for home care stays. I couldn't agree more about not adding another party to involve -- rather, aligning the incentives from a standpoint of managing a population, I just believe has a great deal more hope for getting everyone on the same page, looking for the best outcomes for the patients.

The investments that our partners and skilled made I information technology to be a part of the work we were doing in the Pioneer was quite amazing, and their willingness to achieve the Stars rating. So I think once you align incentives, we can accomplish a great deal.

DR. CROSSON: But, Sue, you could see, for example, the rationale for the Pioneer ACO functioning in this way as part of it. Yeah. All right.

So, again, we're getting a little tied up in the terminology and language here, but not necessarily saying that Pioneer ACO is an insurance company, but it has undertaken a level of risk, which historically was done by insurers, so okay.

Okay. Jack and Mary and Cori.

DR. HOADLEY: So I don't know if we're giving

more attention to the third-party vendor theme than perhaps among all the other issues, but I guess the one thing I would add on that point is -- I mean, what appealed to me initially when I heard that was that notion that -- and you reflected some of that in the experience you heard -- is that it really can become the patients, the beneficiaries, advocate in helping to think through the choices. And the more I sort of hear that vendor become financial risk and some of that, then I don't see it serving that same sort of beneficiary perspective kind of thing.

Maybe there's a simpler kind of role. I almost think about the kind of navigator role in the ACA exchanges or something somebody -- and this would have to be more sophisticated than those are. Those are picking among insurance plan options. You know, like you said, the kind of use of data and things, it takes that up a level, but maybe there's different functions for where the health system should provide the sort of at-risk or the bundling kind of thing versus the person who sort of helps that patient become empowered to make a choice of where they want to go, understanding some of the financial and quality-of-care consequences.

The other thing I wanted to comment on -- and you didn't bring this up in the presentation, but you have it in the paper, was the cost sharing. It is kind of striking. We've talked about cost sharing lots of times, and it's kind of striking to put them side by side for these four types of vendors. In one case, you've got no cost sharing. In one case, you've got 20 days of none, and then costs are added. And the other two, you've got basically 60 days of no cost sharing -- and I think I'm oversimplifying this slightly -- and then cost sharing kicks in, depending on whether there's been a prior hospital stay and all that.

Your header for that was need to standardize cost sharing to reinforce the site neutrality, and that seems like something that is important to think about. And it does seem like there's a common side of the four sectors where you start out your post-acute stay without cost sharing, and the cost sharing kicks in at some point in time or in one case doesn't. And I don't have an answer at this point, but I think thinking about whether that's the right model of some period of no cost sharing followed by cost sharing or whether there should be some -- more of a -

- if we're thinking of these things in a different kind of payment model, whether it's more of a one-shot kind of thing. But I think it would be useful somewhere down this process to think about what are some of the options or how that could be structured in a way that doesn't add unreasonable burden to beneficiary out-of-pocket cost but does the kinds of things we would normally look for.

DR. CROSSON: Mary.

DR. NAYLOR: So I just want to reinforce. We've just come from, I think -- I don't know how many focus groups with beneficiaries and family caregivers, and the number one theme, concern, question, comment was around continuity. As we're addressing, it gets to what everyone is saying, addressing gaps in systems, of the solutions have been yet one more care manager, so that the day after discharge, the payers are calling and the health system is calling and primary care is calling.

So I've gone over this, but I think that it really speaks to what are the possibilities here to really think not just about continuity within the context of movement during the PAC post-acute journey, but also the connectivity between the acute and post-acute and primary.

And so I would really speak to a kind of payment model that promotes that continuity, whether it's in primary care or ACOs, but really vesting responsibility for a trusting relationship with a clinician who can help in decision-making about whether or not someone is ready to move from the skilled part to home health or go straight home, not just to be brokering services, but really engaged in the whole process.

On the continuum of services, I think I'm just a little concerned about the way we think about some of these policies, whether or not we think about them both -- not wanting to prevent skimming or moving people quickly out of systems, which is one end -- and we have to be concerned about that -- but the other is to think about ways in which we can use the policy to really enable movement to match the right set of services. So I think it's a balance here as we go forward.

I really like moving towards a value-based purchasing and resource and thinking about the measurement of what's value in the post-acute and the way that we've been thinking, about the experience with care and function and quality of life along with it, because that's what

people will tell you matter to them -- and some measure of continuity.

DR. CROSSON: Cori.

MS. UCCELLO: So I would like to sign on as a cosponsor to Jack and Mary's comments on the idea of finding ways to empower the beneficiaries, to help them in their decision-making process and how they are guided to the appropriate facilities. I think that's an area that really needs a lot of work.

And in terms of this third party, to kind of decide from that issue of taking the beneficiary perspective, to the extent that this is more trying to, from a facility perspective and as a financing cost perspective, is this something that even if we thought it was a good idea, which it's not clear that we do, but it's not clear that it would need to be done separately through a Medicare mechanism, that it could just be done already? The hospital, if they're vested here in how the patients that are moved on to the PAC, you could see some relationships between the hospital and this third party that help guide those decisions. That could be out of the scope of Medicare payment policy.

DR. MILLER: But, Cori, in that instance, in this case -- because I think this issue is one we've got to talk because there's differences of opinion. We're using different words, "navigators" versus -- and I need to eventually draw a bead on this.

So, right now, if you just went to a unified payment system, in a sense, what you're doing is -- I've more rationalized, assuming all the models work out. All right. I've rationalized how I pay for a given patient, but you haven't, like Sue was talking about, said, "Now, collectively, the providers" -- you used a word "bought in" or, you know -- they aren't necessarily. They are still paid on a fee-for-service basis, and yet everybody is saying, "I don't like a third party," which I get. I'm not taking it on. But somebody needs to coordinate.

Now, one way you can get to that -- and I'm sorry. I'll stop in just a second. One way you can get to that is to make the payment system truly require alignment and coordination where you might draw a circle and say, "I'm paying on an episode now, guys. You guys better get coordinated," and even there, you'd have to kind of decide is there a person who is in charge, give somebody the money

or not. But in the absence of that, you are at once saying "I need coordination" as the most concerning thing that any family talks about, and I hear this all the time too. But I don't want anybody to enter the picture, or I may not want anybody to enter the picture. So how do you guys square that up in your mind?

DR. NAYLOR: fee-for-service plus. I mean, you know, fee-for-service for each of the sectors under a unified payment with a common base and the case adjustment and the outliers, all those core elements of the payment for each of the service, skilled nursing, whatever, but then some care management, something in a system that's trying to integrate it.

DR. MILLER: But that sounds like another person. But I cannot hear you, so I want you to say.

DR. CROSSON: But I thought what I heard you say, Mary, was whoever that manager was, we don't want that to be some extrinsic third party over the telephone. We want that entity person, risk-bearing entity --

DR. NAYLOR: In primary care.

DR. CROSSON: -- to be --

DR. NAYLOR: In primary care.

DR. CROSSON: -- to be --

MS. BUTO: How about the model to primary care physician?

DR. CROSSON: Well, just let me finish. To be intimately involved with the care of the patient so that there's care coordination as well as management, maybe.

DR. NAYLOR: Exactly. Exactly.

DR. CROSSON: Sorry. So --

MS. BUTO: Why wouldn't that? I mean, remember yesterday's conversation about the primary care physician who was taking greater risk from the overall management?

DR. CROSSON: Well, that certainly could be or an ACO.

MS. BUTO: You could add. You could add that element to it.

DR. CROSSON: Right, or an APM, whatever that turns out to be.

Cori was still talking, right?

[Laughter.]

MS. UCCELLO: I think in the --

DR. MILLER: Did those guys allow you to sign on?

[Laughter.]

MS. UCCELLO: They may reject me. I don't know.

I think you're right, Mark, that that -- I think we would prefer to go down Sue's line in drawing a circle around everything. I think that's where we eventually want to go. In the meantime, I was almost thinking that, right, we're still paying on fee-for-service, but there are still some incentives here. The hospitals have their readmission penalties, those kinds of outcomes, measures provide some incentive to make sure that people are going to the right place post-acute.

DR. MILLER: So you might be saying maybe it doesn't -- and I know other people may have other points of view, but it doesn't have to necessarily be a designated person, whether it's an outsider or an insider, to accommodate Mary's point. Maybe the measure signals are enough that the actors are going to want to do it because they don't want to get hit with the readmission penalty or the -- is that what you're saying?

MS. UCCELLO: I think that's what I'm saying, but I don't -- I would not necessarily say that the measures as is are going to be strong enough to create these strong enough incentives. I'm not sure about that, but that's

something.

DR. CROSSON: So, Cori, you're saying it, but you don't believe it.

MS. UCCELLO: I don't know.

[Laughter.]

DR. MILLER: And I'm really not trying to bust your chops. This is -- this is decidedly a tension that I hear here, and eventually, we're going to have to write to it, and so I do want you guys to bat this around a little bit more. And maybe there's not a perfect answer, but I'm just hearing things --

MS. UCCELLO: Well, and part of me was almost trying to bridge this gap in a way to think about, well, if there's not something formal, can this just rise up informally to do that, to do that function, without us setting up some whole new bureaucracy to do it?

Aside from those comments, I just want to add that I really do want us to focus on the monitoring of quality, those kinds of things, to make sure we're not stinting.

MR. GRADISON: May I suggest a quick word on this, just a direct follow-up --

DR. CROSSON: Go ahead.

MR. GRADISON: Because I sort of stirred this thing up. I just would hope in the next step that you would identify what is the risk that -- forget the word "insurance." That tends to be a bad word to use. But there's risk, financial risk here in some way that's being developed, because that's the mechanism, the incentive to try to get the cost and the quality, improve the efficiency. Just identify in whatever model you have, where's the financial risk and what method of assessment can we use to see whether -- where that risk is going to be absorbed? I don't care -- I'm happy to have the hospitals do it. My point was I'm worried about how much risk a hospital -- whether that's their value-added. I mean, that's the only other way I can put it. I'm not trying to say we should build on insurance model -- I mean on insurance companies, but keep -- forget the word "insurance." Risk is the question. How much risk are we talking about? And do we have entities that have a reasonable potential of being able to handle it? That's all I was trying to stir up, and otherwise I apologize.

[Laughter.]

DR. NERENZ: Actually, I think this is an important discussion. If we could just put up Slide 12, and I think this is trying to knit some of this together. When you first showed this, it occurred to me that not only do you have two entities responsible for the area that overlaps vertically. There are really five or potentially five. If in the MIPS environment physicians will now have a component of efficiency in their evaluations, in a typical situation like this, you're going to have a primary care physician who now is in this picture, or has some financial incentive, you're going to have an admitting physician, let's say an orthopedic surgeon for hip replacement. That surgeon is going to be evaluated by what happens in this overlapping space. And if all this plays out in an ACO environment, you've got the ACO who cares about this.

So in this scenario, in looking at this area, the post-acute and maybe immediately after, you could have right now five players, and when we use the phrase "align incentives," that's usually taken to have a positive meaning. But I think inevitably it has this double-edged sword thing where you have five entities who may share the

incentives but disagree completely among themselves about how to achieve the goals.

So mainly to Mary's point, if I'm a beneficiary in this situation, the one thing I really want to know is who's in charge and then, better yet, I want to be able to choose who's in charge. So if, for example, I've made a formal commitment to a patient-centered medical home, primary care, I may specifically want that doctor or perhaps a care coordinator working in there to be in charge of this. And then where I may carry that is to say I would actually be willing to formally declare that, have that entity be responsible formally for the cost, and have the hospital not responsible and have other entities not responsible.

So I'm actually thinking of sort of pulling away some of these multiple players with aligned incentives and from the beneficiary clarity perspective have the beneficiary able to say, "I want my care at least for this period of time to be managed by X," or Y, and be able to choose.

DR. HOADLEY: I don't know if this is my confusion or part of how we're sort of talking about two

different -- somewhat two different things, and it seems to me like one way we're thinking about this is we're developing a new fee-for-service, comprehensive prospective payment or whatever the right PAC payment system, and some of the things we've been talking about are how to -- in a more site-neutral basis, how to help the patient get into the right one of those four settings. And the ideal is taking payment out of the equation as much as we can and trying to let that decision be made on quality, other kinds of things.

There's another layer to this -- and, well, within that there's -- a lot of the accountabilities have to do with some of these, you know, things that Dave was just talking about, the multiple actors who have some stake in the outcome. They're not at risk in a broad sense for the cost of the care. They're at risk in a more narrow sense of they can be dinged or rewarded based on the outcome.

There's another layer we get to talking about which is a broader kind of bundling at-risk kind of thing where it seems like we are thinking about somebody being more -- and that's what, I think, Bill was sort of picking

up on. So either we're thinking the hospital now is accountable, almost more on that sort of first bar, you know, accountable for what's going to go on true at risk where there's, you know, two-sided risk and all that kind of thing, where you do have to worry some about the insurance risks, but it doesn't seem like -- I mean, it seems like those are two different sort of possible ways that the system could be playing out. If it's the first one, there's not really an insurance risk involved. There's a bunch of risks -- "accountability," I kind of like the word better -- and then what we're trying to do is create a means to help the patient get in the right place. That function would still exist in the other system, but now you're either in a broader ACO or you're in a hospital that's accountable for a broader bundle of care kind of situation, and it just seems like we should sort those out and maybe that helps to be where some of the sort of two ways of thinking comes out.

The other thing I would say is for some of these options within either of those ways of looking at it, we may just need to lay out, okay, who could it be, and I like the idea that in some cases these more empowered primary

care providers could play this role, in some cases an ACO could play this role, in some cases the hospital discharge planning kind of function. I mean, they'd do that in a much more narrow way today. There might be other third-party vendors, and maybe just sort of seeing them all side by side would help us sort of think through what are the pros and cons of some of those ways to help with the placement. I'm thinking about, I guess, more in the less at risk kind of first way I talked about it. I don't know if that's helpful.

DR. CROSSON: It is helpful, Jack, and I think you could also imagine over time the entities, you know, evolving from the first level you described, which has a benefit to the patients and to the non-system itself, but eventually having the capability to then take on some global payment risk and do that. But what I'm hearing here is -- and people are using different words, as Mark said, but I'm hearing that there's a thought that there's something valuable in this, but what people don't want to do is parachute in another 1-800, you know, kind of entity, you know, from outside, you know, being paid a bounty for managing the cost. That's not an added value.

But, nevertheless, from the perspective of coordinating for the patient, improving outcomes potentially, but then also, which is one of the three things we're looking at, potentially, you know, for the program, managing the appropriateness of services and the appropriateness of site of service that there's a value to this. And I think that's sort of where it is. It's not -- I don't know, are you ready to work with that or --

DR. MILLER: Yeah, and it looks like Kathy wants to get in, but what I would say as a result of this conversation is I would -- and since I don't have to do this, it's going to be easy.

DR. CROSSON: I don't have to do it either.

DR. MILLER: But I will pay for it. I can tell that.

[Laughter.]

DR. MILLER: So what I would do, if I had to write this up at this point, is I would describe a continuum. One can think of this in the most narrow sense, and I may not get all this right, so just give me a break here. You know, you might want a navigator present to help the patient find their way through the system. Frankly, I

mean, you could want that right now as a matter of fact. And you could talk a little bit about who that might be. Then, you know, you can talk about different continuums of responsibility comprised of actors in the system. There's sort of the -- I'm going to label it as the "Cori Concept." You don't need to be directive. You could just have the measures and that will tend to move people perhaps. That could be part of this continuum. To the very extreme of -- I don't think it could have been put more prejudiced of parachuting a bounty hunter in.

[Laughter.]

DR. MILLER: We'll describe it differently. But, you know, to get the continuum and allow the reader and the Commissioners to see what we've tried to say here, and then, you know, we'll put that in front of you, and then make sure that we sort of argue, I think I'm hearing, more to the left-hand side of that continuum than the right-hand side of that continuum. So if I had to do this, that's what I would probably do.

DR. CROSSON: And you would be right.

DR. MILLER: Kathy would change all that.

MS. BUTO: Mark is always right. So I would just

-- I like the way Mark just framed that. I jumped to the end of the paper and looked at the thinking that went behind, you know, maybe what we need to be evolving toward is uniform standards and criteria. If you imagine a world like that, that would be on the far end. Then it becomes really a choice between home health and institutional. And then the choices are driven more by -- because payment shouldn't be driving it anymore. It should be driven more by quality scores, resource use, you know, other measures of goodness or quality or whatever.

So I think on that continuum, you could imagine if we ever got to that point -- and I guess I do ask the question: Is there any rationale to have different institutional providers? And we probably should talk about that at some point, because if there is, then we'll never get to that state. But if that's where you end up, then you don't need a big navigator function at that point. What you need is some help with the quality scores, and is this person homebound and needs to be at home, versus would do better in an institution. So your choices then don't become so muddled, it seems to me. But I don't know if we're there yet. It is suggested, and it made me think

about the choices get simpler once you get to that point.

DR. BAICKER: So just to layer another axis on Mark the Bounty Hunter's continuum --

DR. MILLER: That came out of him.

[Laughter.]

DR. BAICKER: So you can imagine on one end a payment structure that is driving patients towards higher-value sites of care, regardless of whether that's the right site for them, and on the other end, payments that are driving patients towards the right site of care for them that gives them -- achieves a quality benchmark at the lowest price possible. And the site-neutral payments that we're working towards with this would remove the push towards the more expensive care, regardless of whether it's appropriate. And then kind of -- and I think we're all agreed we don't want to be pushing people there. Being completely neutral doesn't -- lets patients sort out independent of the payment, but it doesn't guarantee that they end up in the right site. And now we're talking about is there a way to actually push towards a system that is predisposed to putting patients in the right site, not just neutral about which site they go to. And there are a

couple of different levers that we're talking about. You can be activist about it and pay somebody to coordinate and, you know, align payment incentives for somebody who's not an individual site to get people into the right site. Or you could have a payment structure that is about the efficient site of delivery where it's just not going to be cost-effective to treat a patient in a really expensive site of care if it's not appropriate for that site of care, and in some of the other models we see, like, you know, shared savings in ACOs or things like that. We're kind of trying to line up the incentives and letting the providers sort it out amongst themselves if the incentives are lined up. And we're not there yet with this post-acute care, how to get from neutral to promoting efficient use, and that's I think what we're struggling with. But the first step in saying we're at least not going to be pushing people into the expensive sites is a more clear-cut step in the right direction, and then how that plays out as we get more data, I think we'll get more information about how well that performs in sorting patients out and what additional levers might be necessary to get to the other end of the continuum.

DR. CROSSON: Thanks. Very helpful and penultimate comment. Rita?

DR. REDBERG: I just wanted to build a little bit on where Kate left off, because I agree, I think the site-neutral kind of payment -- and, of course, I would just suggest the way to work towards better outcomes and making sure that patients are in the right place is just -- as you said, we need more data and sort of a tracking, you know, a learning health care system where, you know, we are -- we have perhaps an electronic health record, some way of understanding what patients went into what kind of settings post-acute care and how they did, and then we can continuously learn and, you know, refine the model as you're doing so that we know what characteristics and what kind of care patients need and how they do better.

But, again, you know, having it tracked on outcomes and not on, well, they went to an IRF or a SNF and we're going to pay for that, but having a more site-neutral and adjusting the level of service to what patients need and how they'll do better as opposed to a payment.

DR. CROSSON: Okay. I think this has been a good discussion. I'm not going to attempt to sum up because I

think Mark, Kate, and several others have done a pretty good job summing up already, and I hope, Carol and Dana, that you've gotten some good information from this, and we look forward to seeing you again. Thank you very much.

[Pause.]

DR. CROSSON: Okay. I think we're ready to go for the last presentation and discussion for the November meeting. We're going to have a discussion about dual-eligible beneficiaries. This is a status report, but it also is, I think, a setup discussion to help the staff in what is going to be a series of site visits next year into Medicare demo sites, so that in the next term, we can come back in more detail, informed with the knowledge base that's being created.

So, Eric, you're going to take us through this presentation? It's all yours.

MR. ROLLINS: Thank you.

Good morning. Today I'm going to give you an update on our work on individuals who receive both Medicare and Medicaid benefits. These people are commonly referred to as "dual-eligible beneficiaries."

I'd like to start by giving you a quick overview

of the presentation. I'll begin by briefly reviewing the dual-eligible population, touching on such issues as how people become dual eligibles, and how their health and Medicare costs compare to other beneficiaries.

After that, I'll recap some of the work that the Commission has done in recent years that directly affects dual eligibles. I'll then review the role of the Medicare Savings Programs, or MSPs, and present some illustrative scenarios for expanding them.

I'll conclude by reviewing the demonstration projects that CMS has approved for the dual eligibles and outlining our plans to prepare a status report on them. We plan to present this update to the Commission in the spring.

Moving now to slide 3, there were almost 10 million dual eligibles in 2014. They are commonly divided into two groups -- full-benefit duals and partial-benefits duals -- based on the type of Medicaid benefits that they receive.

Full-benefit dual eligibles typically qualify for a wide range of primary and acute care services, as well as various kinds of long-term services and supports, such as

nursing home care.

In contrast, partial-benefit dual eligibles only receive assistance with Medicare premiums and, in some cases, cost sharing.

To become a dual eligible, you must separately qualify for both Medicare and Medicaid. About half of dual eligibles originally qualified for Medicare due to disability, which is a much higher rate than for the overall Medicare population. On the Medicaid side, about half of the full-benefit duals qualify because they are eligible for Supplemental Security Income benefits.

Partial-benefit duals qualify through the MSPs, which I will discuss in more detail later in this presentation.

The next slide provides some high-level characteristics for the dual eligibles. As a group, they are much more likely than other Medicare beneficiaries to suffer from multiple chronic conditions. They are also more likely to have some type of mental illness. For example, 18 percent of dual eligibles have Alzheimer's disease or some related form of dementia. They are also much more likely than other Medicare beneficiaries to

report that they are in poor health. As a result, Medicare per-capita spending for dual eligibles is about twice as high as it is for other beneficiaries.

Overall, the dual eligibles account a disproportionate share of total spending in both the Medicare and Medicaid programs. In 2010, they accounted for 34 percent of total spending in each program, even though they only represented about 20 percent of Medicare enrollment and 14 percent of Medicaid enrollment

Now I'd like to briefly review some of the work that the Commission has done in recent years that relates directly to the dual eligibles.

Broadly speaking, the Commission's work has been driven by two key areas of interest. The first area has been the eligibility rules that define the dual-eligible population and the roles that Medicare and Medicaid should play in paying for their care.

In 2008, the Commission examined the Medicare Savings Programs and recommended raising the MSP eligibility limit to match the Part D low-income subsidy, which would increase the number of partial-benefit dual eligibles.

In 2012, the Commission recommended a number of changes to Medicare's benefit design, such as adding an annual cap on out-of-pocket spending and combining the Part A and Part B deductibles. These changes were designed so that the aggregate cost-sharing liability for all Medicare beneficiaries would remain the same. However, the cost sharing for individual beneficiaries could rise or fall, depending on their circumstances.

These changes to the benefit design would affect Medicaid because it often pays for cost sharing for dual eligibles. The changes could also spur interest in expanding the MSPs because cost sharing would increase for some beneficiaries who have relatively low income but currently do not qualify for assistance.

The second area of interest for the Commission has been developing or expanding the use of new models of care for the dual eligibles that could reduce costs or improve the quality of care. Many of those models involve the greater use of managed care.

In 2012, the Commission made recommendations to expand the use of the PACE program, which serves people who are 55 or older and need nursing home care. The program's

goal is to serve those beneficiaries in the community and keep them out of nursing homes, and most of its enrollees are dual eligibles.

In 2013, the Commission examined Medicare Advantage Special Needs Plans, which serve three types of beneficiaries with special needs: dual eligibles, those living in institutions such as nursing homes, and those with certain chronic conditions. The Commission concluded that, in certain cases, SNPs were one way to better integrate care for beneficiaries.

In the next several slides, I am going to focus on the first area of interest by reviewing the Medicare Savings Programs and discussing the potential implications of changing their eligibility rules and financing. After that, I'll turn to the second area of interest and discuss the demonstration projects that CMS is now conducting for dual eligibles.

Under the Medicare Savings Programs, state Medicaid programs are required to pay for Medicare premiums and, in some cases, cost sharing to certain groups of low-income beneficiaries. This slide shows the eligibility limits and benefits for the MSPs and includes information

for the Part D low-income subsidy for comparison.

As you can see, the benefits provided by the MSPs vary by income. The poorest beneficiaries, those with income below the poverty level, are covered by the Qualified Medicare Beneficiary, or QMB program. This is the most generous MSP, covering Part A and Part B premiums and cost sharing.

The other two MSPs -- the Specified Low-Income Medicare Beneficiary, or SLMB program, and the Qualifying Individual, or QI program -- provide assistance with the Part B premium to beneficiaries with income between 100 and 135 percent of the poverty level.

The costs of the QMB and SLMB programs are divided between the federal government and the states, while the costs of the QI program are paid entirely by the federal government.

By comparison, the Part D LIS has a higher eligibility limit, which you can see in the column farthest to the right. The LIS covers beneficiaries with income up to 150 percent of the poverty level, compared to the MSP cutoff of 135 percent. However, the LIS does provide less generous assistance for beneficiaries in that final income

range of 135 to 150 percent.

Finally, it's not shown on this table, but the MSPs and the LIS also require beneficiaries to have assets, such as bank accounts, below a certain level in order to qualify for benefits. However, the LIS asset limit is higher than the limit used for the MSPs.

Moving on now to slide 7, there are some key issues to keep in mind when considering the role of the MSPs.

First, research has found that many beneficiaries who qualify do not participate due to factors such as a lack of awareness that the programs exist and the difficulty of applying for assistance.

When the Commission examined this issue in 2008, it found that the low participation rates were partly due to the fact that the eligibility rules for the MSPs and the LIS differ, as we saw on the previous slide.

Second, there are also important differences in how people sign up for the two programs. Beneficiaries apply for the MSPs through their state's Medicaid program, and those who qualify are automatically enrolled in the LIS. In contrast, beneficiaries apply for the LIS through

the Social Security Administration. The SSA does not screen those applicants for MSP eligibility, even though many are likely eligible.

Third, Medicaid allows states to limit how much cost sharing they pay for beneficiaries enrolled in the QMB program. States do this through what are known as lesser-of policies, which use the lower of the Medicare rate or the state's Medicaid rate to determine how much cost sharing will be paid for a given service. Most states use lesser-of policies for at least some services.

In addition, when states limit their payment of cost sharing, providers cannot bill QMBs for the remaining unpaid amount, so lesser-of policies ultimately reduce their overall payments.

Finally, research also indicates that the use of lesser-of policies may reduce access to care for QMBs.

A variety of researchers and advocates have proposed expanding or federalizing the MSPs to achieve goals like increasing participation rates or providing fiscal relief to states.

To give the Commission a better sense of the issues involved, staff developed three scenarios to

demonstrate the effects that expanding the MSPs could have on participation rates, federal spending, and state spending. These scenarios are purely illustrative and not a substitute for the budgetary estimates that CBO produces for Congress.

Each scenario would align the eligibility rules for the MSPs with the Part D low-income subsidy. This means that the income limit for MSP benefits would be increased from 135 percent of the poverty level to 150 percent and that the asset limit for the MSPs would be increased as well. Since the MSPs and the LIS would have the same eligibility rules, all three scenarios also assume that the SSA would be required to screen applicants for both MSP and LIS eligibility, and would enroll those who qualify in both programs.

The first scenario repeats a recommendation that the Commission made in 2008. The eligibility limit for the Qualifying Individual program, which provides assistance with the Part B premium, would be raised from 135 percent of the poverty level to 150 percent. The cost of the assistance for these newly eligible beneficiaries would be paid for entirely by the federal government.

Under the second scenario, the eligibility limit for the QMB program, which provides assistance with Part A and B premiums and cost sharing, would be raised from 100 percent of the poverty level to 150 percent. The costs of the program would be paid partly by the federal government and partly by the states, and states would be able to use lesser-of policies to limit their payments for cost sharing.

The third scenario is the most far-reaching. Like the second scenario, the eligibility limit for the QMB program would be raised to 150 percent of the poverty level; however, the program would be federalized and become part of Medicare, which would pay the full amount of cost sharing for those enrolled. The costs of fully covering the cost sharing would be partly offset by lower spending on bad debt payments.

Finally, states would also be required to make maintenance-of-effort payments to the federal government based on their historical MSP spending. These would be similar to the so-called clawback payments that states now make under Part D.

The next slide summarizes the impact of these

three options on MSP participation and combined federal and state spending. For more detailed information about our estimates, please refer back to table 4 in the paper.

We estimate that all three scenarios would increase the number of people enrolled in the MSPs by roughly 2 to 2.5 million people. Most of the new enrollees, about 1.4 million, would be people who now receive LIS benefits but are not enrolled in an MSP. The other 500,000 to 1 million people would be truly new participants that currently do not participate in either the MSPs or the LIS. We also anticipate that MSP participation rates would be higher under each scenario than they are now.

As for the 10-year costs, we estimate that total spending would increase by $46 billion under the first scenario, $111 billion under the second scenario, and $296 billion under the third scenario.

Under the first scenario, the increase in state spending, which is not shown on the slide, would be relatively small because the federal government would pay the full cost of expanding the QI program.

The costs of the second scenario would be more

than two times higher because the second scenario would also provide assistance with cost sharing for beneficiaries with income between 100 and 150 percent of the poverty level. This would lead to higher costs for the existing MSP enrollees in that income range, and we anticipate that the more generous assistance would also result in more new enrollees. However, the MSPs would continue to be funded by both the federal government and the states, and states could still limit how much they pay for cost sharing. We believe that many states would continue to do this, which would reduce the cost of the second scenario.

Like the second scenario, the third scenario would expand assistance with cost sharing, but the MSPs would be federalized, and Medicare would pay the full amount of cost sharing. We believe that, in aggregate, states now pay about 35 percent of the cost sharing for QMBs, and it's the cost of covering the other 65 percent that accounts for the difference in costs between the second and third scenarios.

More than half of the cost of the third scenario would be additional spending for people who are already enrolled in the MSPs, as opposed to new enrollees. I

should also note that savings from lower bad debt payments have been included in the estimate for this scenario.

States would normally see significant savings from federalizing the MSPs, but we assumed that they would be required to make maintenance-of-effort payments that would effectively eliminate any savings. Without such a requirement, the total costs for the third scenario would not change, but federal costs and state savings would be much higher.

Although a maintenance-of-effort requirement would partly offset the costs of federalizing the MSPs, it would also create inequities across states. This slide provides figures for two states as an example. The figures shown here have been rounded for ease of presentation, but they're based on actual data.

In 2012, the total amount of cost sharing for QMBs in the two states was roughly the same, at about $100 million. Neither state covered the full amount of the cost sharing, but state A paid a much larger share, about 70 cents on the dollar, on average, than State B, which paid an average of about 35 cents on the dollar. Given each state's Medicaid match rate, those payments translated

into about $22 million in state spending for state A and about $13 million for state B. Those state spending amounts would be the basis for the maintenance-of-effort payments under our third scenario, which means that state A would make larger MOE payments than state B. However, state B stands to benefit more under the scenario, as Medicare provides $65 million in additional funds to providers in that state, compared to only $30 million for providers in state A.

The next slide, slide 11, summarizes some findings from these illustrative scenarios. First, the number of new MSP enrollees under each scenario would be relatively small, which is due partly to the difficulties involved in getting more people to participate.

The second scenario would expand eligibility for assistance with cost sharing, as well as the Part B premium; however, the existing structure of the MSPs would be largely unchanged. This would reduce federal costs in two ways. First, states would pay part of the cost of expanding the MSPs, and second, states would continue to use lesser-of policies to limit their spending on cost sharing.

Finally, the third scenario, expanding eligibility for assistance with both premiums and cost sharing, and federalizing the QMB program, would be the most expensive. This is largely because Medicare would pay the full amount of cost sharing and would thus bear costs that the states have chosen not to pay.

Requiring states to make maintenance-of-effort payments could offset some of the costs of federalizing the MSPs, but it would also lead to lower savings for states and create inequities across states.

I'd like to note that this list is not exhaustive. There are a number of other issues that would need to be addressed as part of expanding the MSPs, particularly as part of federalizing the program; however, these kinds of proposals aren't being widely considered right now. If anything, policymakers are more focused right now on initiatives that in some ways give states a greater role in caring for the dual eligibles.

With that, I'll now turn back to the Commission's other key area of interest for the dual eligibles, which is the development of new models of care.

In 2011, CMS launched what it calls the Financial

Alignment Initiative, which encourages states to test new methods of integrating care for full-benefit dual eligibles. Under the initiative, states can conduct demonstration projects that test two different models. The first is the capitated model, which uses managed care plans to deliver both Medicare and Medicaid services to dual eligibles. The second is called the managed fee-for-service model. Under this model, states can provide greater care coordination through their Medicaid fee-for-service programs and can receive a portion of any resulting Medicare savings.

The first demonstration project approved as part of the initiative is in Massachusetts and began operation in October of 2013.

A total of 13 states are currently conducting demonstration projects under the initiative. Most of those states are testing the capitated model. Only two states, Colorado and Washington, are testing the managed fee-for-service model. Another state, Minnesota, is testing an alternate model that integrates some administrative functions for plans that serve dual eligibles. As of last month, about 450,000 dual eligibles were enrolled in these

demonstrations.

Turning now to the last slide, staff are planning to deliver a status report on the demonstration projects to the Commission in the spring of next year. As part of this effort, we will make site visits to several states with demonstration projects and will examine a broad range of issues, such as the use of passive enrollment, the kinds of care coordination that plans and states are providing, the impact of those efforts on service use and spending, and the adequacy of the rates that CMS and states are using to pay participating plans.

Given the wide range of issues that are involved with these demonstration projects, we would welcome input from the Commissioners about specific topics that they would like us to address in the status report.

That concludes my presentation. I will now be happy to take your questions.

DR. CROSSON: Okay, Eric. Thank you very much.

So we're open for clarifying questions. Kate, Jack.

Jon, would you do this?

DR. BAICKER: So this was really helpful. Thank

you.

And I was interested in the scenarios for expanding dual-eligible coverage. You accounted for a couple of different mechanisms, and I wasn't sure about a couple of additional mechanisms. So you accounted for new people signing up. You accounted for -- or new people being eligible for the MSP programs. You accounted for increased federal share of the existing people who were already on the programs. Did you build in a change in use of services because of the additional coverage for both the new and the existing people, which seems like it could be potentially big? And then a fourth one, which seems like it probably isn't so big, which is the different marginal characteristics of the new enrollees, meaning they're different kinds of utilizers, although it sounds like there aren't so many new enrollees, so that's probably smaller.

MR. ROLLINS: So, in terms of service use, I think, directionally, we think that enrolling more people in MSPs would tend to increase their service use. We didn't explicitly account for that here. Dealing with -- figuring out what the magnitude of that increase is requires you to have some notion of what their coverage

situation looked like before they enrolled in the MSPs. If they truly had no coverage or were otherwise uninsured, then I think, clearly, yes, their service use would go up.

But, for example, to the extent that people are moving out of MediGap plans, which now currently provide this, essentially, level of coverage now and into this, the impact may be less significant.

DR. HOADLEY: So I had two clarifying questions. On slide 10, you talked about, in the last bullet, the state would have a larger MOE payment, state A, but state B benefits more. And here, you're talking it benefits sort of broadly to the state and its medical system, not to the state budget. Is that right?

MR. ROLLINS: That's correct.

DR. HOADLEY: Okay.

DR. MILLER: It's really the providers in each state.

DR. HOADLEY: Yeah, the providers in the state.

And then my other question is a little more general, which is, how good are the data at this point on the number of people who are eligible today but not enrolled? I know on Part D LIS, we struggled to get sort

of a good denominator of how many are eligible, and I know that's -- I think that's been a struggle here as well, but I wondered sort of your assessment of the data.

And then related to that, when you talked about higher -- in your scenarios, when you talk about higher participation, are you assuming any increase in enrollment among the eligible today but not enrolled, as opposed to the newly eligible?

MR. ROLLINS: So, in terms of the quality of data, it has been a struggle. I would say that it continues to be a struggle. There's simply no data source that everyone seems to feel comfortable with that has a picture of both income and, in particular, asset eligibility for these individuals. And for all of these scenarios, we assume that both of those criteria would still be in play. So that's a data problem. As you noted, it's been around for a while, and I'm not aware of anything that's going to help us definitively resolve it.

In terms of -- your second question was? Remind me.

DR. HOADLEY: Whether you're assuming any increase in enrollment by the currently eligible but not

enrolled.

MR. ROLLINS: We did for the second and third scenarios because for people in that 100 to 135 percent range, right now they're eligible just for assistance with their Part B premium. We would anticipate that if you also made them eligible for assistance with cost sharing as well, that's a better benefit package, and so some of the people who are now eligible but not enrolled will sign up.

DR. HOADLEY: Okay. Thank you.

DR. CHRISTIANSON: Cori, did you have anything?

[Speaking off microphone.]

DR. CHRISTIANSON: Alice.

DR. COOMBS: Just quickly, just the impact -- because I'm interested in the Massachusetts Demonstration Project and what the outcome of that is because I've spoken to a couple of people in the state office who told me what they're doing, which is really interesting in terms of trying to work the two systems together.

What about the impact of ACA with some of the other states and expansion in the scenarios? In other words, how do they impact the scenarios?

MR. ROLLINS: In terms of the Medicaid expansions

or the marketplace with the exchanges?

DR. COOMBS: Well, in terms of the Medicaid --

MR. ROLLINS: The Medicaid expansion targets a different population than what would be effective here for the dual-eligibles. The Medicaid expansion was essentially for people who are not aged or disabled and have income below 138 percent of the poverty level, so it's a different subset than the folks that we're talking about.

DR. COOMBS: So there's no overlap between the purely disabled who become a part of the Medicaid expansion? Is there not an overlap?

MR. ROLLINS: No, there's not an overlap, but the eligibility rules for the aged and disabled were not affected by the Affordable Care Act.

DR. CHRISTIANSON: So, Jack, you were going to kick off the next round?

DR. HOADLEY: Yeah. And thanks, Eric. I mean, this was really helpful going through a lot of very complicated stuff.

It seemed like -- and I'll make comments on both, the sort of eligibility and financing stuff, and then the new models and some issues you might look at on the site

visits.

It seems to me like I hear sort of three major sort of reasons to make some kinds of changes or issues that have arisen in terms of the eligibility and financing aspects. One is this notion that the participation rate is lower than we would like it to be and particularly for the MSP side. And it seems like there is a number of things -- and you talked about several of these -- the complexity of the rules, people's awareness that there is a benefit out there. I would also add that just the existence of an asset test, which partly because it adds sort of complexity, adds a little bit of stigma, and sometimes we think it will just scare people away because they don't want to get into a discussion with government officials about what assets they hold. And so that's one issue that we could see some improvement on.

The second is just the ability to provide broader help or more help to a broader set of people, and that's the notion of providing cost-sharing assistance further up the income ladder.

And then the third, I think -- and you talked about this as well -- is just the inconsistencies across

states and how they interpret policies and how they implement policies. I've looked at some of this stuff on eligibility, and you see a few sort of large differences where there's at least three states that completely eliminate the asset requirement, so that's a broadening of eligibility. That's sort of easy to understand. But where you get into the really detailed complexity is which kinds of income are offset, what kind of assets are offset, and I've had a project where I needed to look at some of the differentiations. And it is very hard to figure out, "Okay. So does this little source of income count?" And there's no federal standard on those kinds of things, so that makes something like the federalization scenario certainly have some appeal.

And then, again, you talked about this in terms of the lesser-of policies and how the cost sharing is covered, and that has an impact not only on access, but also on sort of providers' ability to cover their costs.

And lately, there have been some issues around balanced billing. There have been providers who have sent -- who have billed beneficiaries. As you've said, correctly, they're not allowed to do that, but there have

been instances where that's been happening lately, and there's been attempts to enforce some crackdown and make sure that doesn't happen. But it's sort of created like this.

I don't know whether this is the kind of area. Obviously, in your three scenarios, scenario 1 is one where the Commission has already spoken and said something either identical to scenario 1 or something very close to it is in current Commission recommendations. I think there would be value in going beyond that, certainly reinforcing and restating that, those old recommendations, as we have done before, but potentially going beyond it to some of the other levels, obviously, there's a big leap when you get to scenario 3 in terms of the cost.

But I think, you know, trying to think about how to simplify eligibility, how to create more of a level playing field across different states, on the other hand, not wanting to take away where certain states have made much more generous rules and decided, using their own funds, to make eligibility -- partly their own funds, make eligibility more generous, wanting to affect that, but I think some of the detail where states differ is having a

negative impact, both on beneficiaries and in the case of loss are on -- on the providers.

I think on the other side of the issue, on the new models, I'll give you a few suggestions of things, and I've taken a look at one of the financial alignment demonstrations in Virginia. And I know the Commission has in its comment letter on these, has raised issues around the past of enrollment, and I think one of the things you can potentially see in the states is how that's played out.

I know in Virginia, there was issues around sort of their ability to do an intelligent assignment process, which they intended to do, and most states that have these programs do intend to do, but they have ran into some severe data issues and getting the data they needed from CMS to do it the way they originally wanted to do it.

And then opt-out rates have been a big issue. Anybody who has looked at these at all has seen the high level of opt-outs and trying to understand what -- some of that seems to be provider driven, and so just trying to get a better sense from the states that you talked to about sort of what they think is going on with those opt-out rates.

Another issue that I've thought about lately is sort of -- this is a time-limited demonstration, and it's actually not for all that long a period of time. So states spend a lot of time ramping this up, getting -- going through a lot of challenges and implementing, and then the demo is going to come to an end, and sort of how states are thinking about -- sort of doing something -- you know, how they're doing something if they feel like they've made some progress, does that go away? Do they have ability to sort of keep it going beyond the life of the demo? In other cases, you've got states that are doing other kinds of managed care, Medicaid managed care initiatives, which would not have all the features of the financial alignment with the coordination with the federal dollars and sort of what's going to be the impact, so sort of thinking forward sort of how that might play out over a couple of years.

And then I think the last area I would comment on or would hope you would look at it sort of what's the real change we're seeing in terms of care coordination and care delivery.

When we look at look at Virginia, it was early on, and I think the general consensus was they haven't

really gotten to that phase of it yet, which also relates to this question of the length of the demo. How much time does it take just to ramp the thing up? And then you've got to start implementing good ideas on how to coordinate care, and will we have a chance to see real results? Are there in fact, when you're out there looking, real results they can point to in terms of better coordination, or is it mostly still aspirational? We've got this idea. We think it can happen, but can we point to any results? No, not really -- and sort of which answer is.

And then I think as you're doing that, to what extent are we seeing too much coordination? So there's the potential for the new MCO to come in and coordinate, but there's already the potential for the SNF, and many of these people are in long-term care or somebody in home and community-based care, so there's a coordinator there. There is perhaps a primary care coordinator, and maybe they're also in an ACO. Maybe they're in a patient-centered medical home. Maybe a person with disabilities who has a personal care assistant that's trying to coordinate their care -- and they could be sitting with four, five, six different coordinators, and then do you

need a coordinator to coordinate the coordinators? Maybe that's not a problem, but I think I've seen enough instances when I've been on site myself in some of these, to hear these kinds of things. Well, the plan comes in, and there's really not a useful role for them to play because they're either getting good coordination already or it creates complication because now this is a telephone coordination as opposed to the much more personal version that they're getting through some other sources.

So I think those are a number of things I would put on the table for things you may look at within the site visit framework, but I'm really encouraged that you're doing the work.

DR. MILLER: Yeah. And I would just -- I think those are all good ideas. You should add to them as you go around.

On the opt-out, we do keep hearing this: This is very provider driven. And, I mean, this is one area that we want to look into, and I don't know whether that's just people are saying that or whether it really seems to be happening. It seems like you came across some of that.

DR. HOADLEY: Yeah. We saw some of that in

Virginia, and this is all written up in a report through Kaiser Family Foundation, so our results are available, and I'm certainly happy to share more about it, but there were certainly -- and they were not sure, all the sources, but they certainly did have some cases where they would get a whole list of beneficiaries from one particular nursing home saying, "We want all these people opted out," or they would just get a sequence of letters that looked like form letters, again, probably generated in most cases by a nursing home. In some cases, the state would then sit down with the nursing home and say, "Do you really understand what we're trying to accomplish here?" and try to work with them. And it tended to sometimes be the small independent nursing homes who just didn't know much about what was going on, and they were afraid this was going to mess them up, they were going to lose their patients, whatever.

In other cases, it's not so clear that it was generated that way. It may have just been some more generic -- but they were working, and we had a point at which we had to finish our report. But they were continuing to explore and do some focus groups and surveys with some of the opt-out folks and trying to understand

what their motivations were. So maybe by -- you will be in the field well over a year beyond when we were in the field, and it would be similar in Massachusetts or Ohio or some of the other early states. You may be at a point where they have now a better sense of what went on and whether some of those people have reenrolled, because there was some concern about too much churning, but also some sort of appropriate, coming back into the program, because they would reach back out to the opt-out people and say, "Let me give you more information and see if this is something you might want to withdraw your opt-out."

DR. MILLER: The other thing I would ask you to comment on, particularly anybody who has gotten close to this in their own states or exactly what he said. He put -- I think you put it really well.

There's been a lot of like getting -- identifying the population, enrolling the population, getting the plans in, and making everybody understand what's going on. And then there's to do what? What is the special plan for the mental health population, the disabled population?

If you've heard of there is a particularly interesting program or angle on things, we want to know

about that because that's what we would like to be able to bring back.

I'm sorry.

DR. HOADLEY: Yeah. I think in Virginia, we heard actually very good reports in terms of the states working with all the stakeholders to try to sort of get them going, but there was a lot of start-up time involved in Virginia. In particular, it didn't have a big managed care history for this population, like some other states, and we would hear from one of the particular plans out there, a very interesting model, I think, and exactly in the behavioral health area where they wanted -- I forget exactly the nature of it, but where they really wanted to do what seemed like potentially could be very creative way to sort of coordinate between medical issues and behavioral health issues.

But it was something they were in the process of trying to get implemented. We were six or nine months into the program when we were there, and, okay, so if it's a three-year demonstration, they're going to get this implemented as of 2.5 years and then have six months to actually let it run, and then it's over, so that raised

some of those issues.

DR. CROSSON: Okay. Jack, thank you very much.

Let me suggest that we do two rounds. We have two somewhat discrete issues on the table. One has to do with a range of scenarios or proposals to expand the Medicare shared savings programs. So I'd like to see where people think they might be on that, and then expanding on Jack's suggestions, if there are any for focus that the staff might take in the site visits later on.

So, on the issue of expanding the Medicare shared savings programs, I saw Kathy's hand.

MS. BUTO: Okay. I don't know where I am on it. Let me just start there. Where I think I am on it is I don't think we're doing a good enough job of outreach under current rules, much less expanding or simplifying the program. And I realize one reason we think there's not a great take-up is it's maybe not looking that attractive, and it's extremely complex to navigate the system.

But I'm wondering whether we could, as we think about this, also consider whether there are things that Medicare could do because I realize the states have mixed emotions about this, but whether Medicare could do more to

make beneficiaries aware that these options exist.

There are certain communications like the annual Social Security notice that people get, other things maybe through their physicians or others, ways that we can think about getting -- using the leverage of the Medicare programs, since these are duals, to make them aware of these options. I just feel like that's a missed opportunity that -- realizing it's a tough one, before we even get to expanding coverage and simplifying.

So that's where I am on that.

DR. CROSSON: Other thoughts? David?

DR. NERENZ: Maybe it's the same thought, just in slightly different words. I think I basically would agree, but it would be interesting -- and I'm not quite sure how you formally do it -- to do some kind of a simulation about where the greatest bang for the buck is in terms of whatever we think the bottom-line benefits are by either getting higher participation in the programs, plural, as currently constructed, or expanding. Because my sense in reading it is the expansion is essentially raising the income limit. Is that the main essence of it, of the "its," plural?

MR. ROLLINS: Yes.

DR. NERENZ: Okay. But if that happens, it's still complex, it's still confusing, and it may still have low participation, but it still may be better. So it seems like there are two big alternatives here. One is to do one of these flavors of expansion and perhaps live with low participation, and that has certain costs and benefits. But you could also say what about pushing to improve participation in the way it currently is, and that has some costs and benefits. And I'd be interested to see those laid out side by side if there was any way to do that.

DR. CROSSON: So on Kathy's point and David's second, is there a history to CMS doing this? Has this occurred before, that is, efforts at outreach? Jack.

DR. HOADLEY: Part of it is, you know, like the LIS created a new opportunity for outreach, and I think the one step where the Scenario 1 actually goes beyond just changing income limits is the idea of aligning the limits with the LIS so there can be a more unified outreach, if you sign somebody up for the LIS, and, again, it's what role Social Security would play versus the states to try to make sure that they at least are told about and maybe, in

fact, enrolled in the MSP side. So that's where I can go a little bit beyond that, and that's actually in the existing things that the Commission has recommended.

There was, I remember -- and I don't remember much of the detail of it -- probably 20 years ago, some initiatives involving the Social Security Administration I think working together with then HCFA to test some different approaches to outreach for enrollment. I don't know how much of that was MSP in particular. SSI I think was maybe part of that. I don't know if, Kathy, you remember some of that. But there were some efforts that maybe showed, you know, the advantages of some different mechanisms. But I don't know that it had particularly encouraging results. I vaguely remember --

MS. BUTO: Yeah, I would broaden the question, Jay, to maybe where has CMS or Medicare been successful in reaching the population to do things that were available but not used.

DR. CROSSON: On any issue.

MS. BUTO: And one example of that would be when the new flu vaccine benefit came in, there was very low takeup. A lot of experimentation went on, and the agency

through its regional offices actually contracted with community organizations, and that was very successful in raising the -- especially in the African American community, raising the awareness that this was a benefit and it was done through the Council of Black Churches, or whatever, with the African American community. So trusted community sources were found to be very effective in getting the word out on these benefits that people were actually already entitled to.

So you could imagine a strategy, if the agency wanted to do it. They were similarly, I think, with Part D, quite -- they've been more and more successful in getting -- raising the awareness both of choices and other things. So they've had the experience, and the question is: Can it be applied to this area? Which is very underutilized and has been for years and years.

DR. CROSSON: So I think I'm hearing support for reinforcing our current recommendations as well as exploring this issue of what CMS could do within the current benefit structure to expand participation. So --

DR. MILLER: And we can certainly review broadly, you know, here's what they did over here and see what

lessons might be brought to bear here.

DR. HOADLEY: Maybe lessons out of some of the Navigator efforts on the ACA side. Again, not always successful. There's also maybe questions of the SHIPs that provide counseling services that are right now facing some funding cuts and that the Commission has talked over the years about, you know, adequate support for SHIP initiatives, and they don't necessarily have -- in terms of some of the state SHIPs have not necessarily been all that successful within some of the lower-income communities or some of the non-English-speaking communities, and so, again, particular efforts potentially to encourage SHIPs to work in some of those areas might be something that separate from, you know, whatever we might do on these scenarios.

DR. CROSSON: Good. Let's then turn to the site visits and the new models of care. Thoughts about -- in addition to the thoughts that Jack has had?

MS. BUTO: The only request I would have -- and I'm sure you're already doing this, Eric -- is to look among the models that you visit for what's being done, targeted, or offered for the under 65 disabled. As you

pointed out in your presentation, a lot of the services there maybe involve mental health care, et cetera, so it dovetails into our other work in that area. But there also might be aspects like personal care services that we should just be aware of the differences in a plan that's going to be serving that population.

MR. ROLLINS: And one of the states that we hope to visit is Massachusetts, which is distinctive among the demonstration states. They're the only ones that's focusing exclusively on the under-65 disabled, and I know mental health issues have been a big concern for them.

DR. CROSSON: Other thoughts?

[No response.]

DR. CROSSON: Okay. Thank you very much. Thank you, Eric. I hope you got some direction here.

So that brings us to the end of our agenda for November, and now we have the opportunity for comments from the public. So if you are interested in making a comment, I would ask you to step up to the microphone so we can see how many individuals are here to do that.

I see one, and I'll just, sorry, reiterate my comments from yesterday. This is not necessarily the only

or best way to provide input to the Commission. There are more direct personal ways as well as online capabilities that exist.

I would ask you to in this case repeat who you are and your affiliation and also try to maintain your comments to two minutes. I will turn this light off, and when the light comes back on, again, that's two minutes. You have the microphone.

DR. LUKE: Thank you, sir. My name is Dr. Josh Luke. I'm the founder of the National Readmission Prevention Collaborative. I appreciate all the conversation today as it pertained to readmissions. I want to thank Carol and Dana for a great presentation, very pointed, and also Eric.

I wanted to just discuss briefly, Dr. Naylor has done such great work in this area, and I appreciated your commentary on it. The Medicare spending per beneficiary measurement right now, my organization has hosted 15 conferences nationally this year focused on care coordination, one-day conferences promoting Dr. Naylor's and other folks' work. There is a significant amount of ignorance to MSPB still in the acute sector, so we have a

lot of work to do to get the message out. But we tend to refer to it at those conferences as the "new readmission penalty" because it's a lot better way to get the acute provider and the physician to pay attention to what happens once the patient leaves the hospital. So I appreciate the focus on that.

I thought, as Carol pointed out, the suggestion for a post-acute MSPB measure was a great suggestion. I would encourage the Commission -- and I'll follow up with Mark and Carol and Dana on this -- to consider possibly extending it beyond 30 days because there is some gamesmanship and some unintended consequences that can come about right at that 30-day mark because the current fee-for-service benefit allows SNFs, for example, to bring patients back on the 30th day, things along those lines. You might have a second episode of home health. So I think it would be important to consider potentially extending that beyond 30 days.

Yesterday there was some discussion on the chronic care management codes, and I would reiterate what the Commission has found as we travel the country and hear from different folks. The beneficiary co-pay is very

prohibitive for somebody on a fixed budget to not really see this care that's being delivered, so that's very prohibited to date. So further conversations about chronic care would encourage the co-pay to be the issue at the forefront, and also from the provider side the documents is absolutely the concern.

And the last thing I would say is I have the honor of being on the advisory board for Global Transitional Care, the first company in the country out in Southern California that's doing transitional care management. We've got 29 patients enrolled. We're doing it at a good pace, and, Mark, your comment about who's going to coordinate as we move forward, again, I can follow up with you on that, but we're starting to see some evidence that potentially having the acute providers hold accountable the post-acute providers, even in an informal network, to do that transitional care piece may be a way to get to that.

So I want to thank you for all the great work that's been done here, and I will follow up on those issues.

DR. CROSSON: Thank you. Thank you for your

comments.

Seeing no one else at the microphone, we are adjourned until December. Thank you [off microphone].

[Whereupon, at 10:45 a.m., the meeting was adjourned.]