MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

The Horizon Ballroom
Ronald Reagan Building
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COMMISSIONERS PRESENT:

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AGENDA PAGE

P R O C E E D I N G S

[9:26 a.m.]

DR. CROSSON: So David, Jeff, and Sydney are here. We're going to do our annual status report on -- I'm sorry. We're going to do a status report on accountable care organizations. Who's going to start? Sydney, go ahead.

MS. McCLENDON: Good morning. I'm here today with my colleagues David Glass and Jeff Stensland to discuss Medicare's accountable care organizations, or ACOs.

To give a bit of background, ACOs are organizations in which participating Medicare providers work together to coordinate patient care. If an ACO provides high-quality care while spending less than what would be expected in fee-for-service Medicare, ACO providers have the opportunity to earn part of the generated savings.

We'll begin today by providing an overview of the different ACO programs for 2016. We'll then discuss our analysis of the 2015 ACO performance results and finish by discussing the possible implications of these findings.

The ACO program has grown since 2015. For 2016,

there are three Medicare ACO programs: the Pioneer ACO Demonstration, the Medicare Shared Savings Program, or MSSP, and the Next Generation ACO Demonstration. This will be the first year for the Next Generation ACOs, and between the three programs there are a total of 470 ACOs serving nearly 9 million beneficiaries.

As you can see on the slide, the MSSP program has more than tripled from where it started. While there are ACOs leaving MSSP each year, there is still an overall net increase for 2016.

Now we'll explore the differences between each of the ACO programs.

The Medicare Shared Savings Program is a permanent part of Medicare and was established in the Affordable Care Act. There are three different tracks an MSSP ACO can choose to participate in. The majority of MSSP ACOs are in Track 1. Track 1 ACOs participate in a one-sided risk arrangement in which they share in generated savings and do not share in losses. ACOs in Tracks 2 and 3 are in two-sided risk-sharing arrangements.

Beneficiaries are attributed at different times for the three tracks. ACOs in Tracks 1 and 2 are

attributed beneficiaries retrospectively at the end of the year, while Track 3 ACOs receive their list of beneficiaries prospectively. Prospective attribution provides ACOs with more certainty as to who they are responsible for at the start of the year. Finally, all MSSP ACOs are paid through fee-for-service claims.

Next we'll look at differences between Pioneer and Next Generation ACOs.

Pioneer and Next Generation ACOs differ from the MSSP program in that both are innovative demonstrations and not permanent programs. Both Pioneers and Next Generation ACOs participate in two-sided risk sharing and are responsible for both savings and losses.

Pioneer and Next Generation ACOs have beneficiaries assigned to them prospectively but differ in how their benchmarks are set. The NextGen benchmark uses only one year of past claims data and has a built-in discount. ACOs that are efficient receive a smaller, more favorable discount.

Finally, Pioneer and Next Generation ACOs vary in how they receive payments for their services. Pioneer ACOs receive payment in one of two ways, the first being

standard fee-for-service. The second option is population-based payments, in which ACOs get reduced fee-for-service payments and monthly per beneficiary payments. Next Generation ACOs have an additional two options which provide them with money upfront. The first of these options is fee-for-service payments with an infrastructure bonus, and the final option is a partially capitated method.

We'll now discuss the results of the Pioneer and MSSP ACOs from 2015, beginning with quality scores.

According to CMS, both Pioneer and MSSP ACOs scored high on overall quality measures in 2015, with averages above 90 percent. Not only was quality high this year, but it improved from previous years.

In a simple correlation, we found that there is a weak, if any, relationship between quality and savings. Pioneer ACOs had a correlation of 0.31 for savings and quality, while the correlation was 0.05 for the MSSPs.

Finally, it is important to note that the majority of the quality scores used are still process measures and not outcome measures. While some process measures are important, they should not outweigh patient

outcomes.

Next David will walk us through the 2015 financial results.

MR. GLASS: So Medicare set spending targets or benchmarks for ACOs that estimate expected spending. If actual spending is less, the ACO saves and can share in the savings. If actual spending is higher, it has a loss. However, as Sydney just showed, the MSSP ACOs do not share losses.

Looking at the Pioneer column first, the 12 Pioneer ACOs had aggregate Medicare spending of about $5.5 billion. The actual spending for their attributed beneficiaries was slightly less, so there was an aggregate savings of $37 million. Medicare paid the ACOs that had savings $34 million in shared savings, and because this is a two-sided risk model, ACOs that had losses returned $2 million to the program. This all yields a net savings to the program of about $5 million, which is 0.1 percent of spending, about breakeven.

In the MSSP column, many more ACOs, thus a much larger aggregate benchmark and spending almost $73 billion. Savings were $429 million, which is similar as a percentage

to the Pioneer at about 0.6 percent.

The big difference is that MSSP was almost exclusively a one-sided model in 2015, so although the aggregate savings were $429 million, the program paid ACOs that had savings $646 million and collected nothing from the ACOs that had losses. So, in net, MSSP cost the program $216 million or negative 0.3 percent. So one could sum up and say, in net, the ACOs had a modest effect.

We just looked at the average financial results for the ACO programs. We now look at the MSSP results for 2015 in some detail.

First, there is a wide distribution of percentage savings and losses for the MSSP ACOs.

Looking at the distribution of savings and losses for the 392 ACOs in the program in 2015, we see about a third had savings or losses within plus or minus 2 percent, and that's the central bar; and the rest were fairly normally distributed except there are more ACOs with savings of over 5 percent than with losses over 5 percent, which accords with the aggregates savings being positive.

The ACOs also vary in location and type. And by type we mean physician ACO if there is no hospital in it

and hospital-based ACO if there is.

We've highlighted the first column, the South. There are 162 ACOs in the South, more than any of the other three geographic areas.

In addition, there are many more physician ACOs than hospital-based ACOs in the South. That pattern is reversed in the MidWest and Northeast, which both have more hospital-based ACOs than physician-based. And this is important because it looks like savings are influenced by these characteristics.

In fact, what many report and what we find as well is that ACOs with certain characteristics have greater savings than others.

First, ACOs in the South tend to have greater savings than ACOs in the rest of the country. And as we noted, there are a lot of ACOs in the South.

Second, physician ACOs tend to have a greater percentage savings than hospital-based ACOs. This point has been mentioned by several researchers.

And, third, small ACOs, which we're defining as those with fewer than 10,000 attributed beneficiaries, are more likely to have savings than large ACOs with more than

10,000 beneficiaries.

However, a key factor that has not been considered in other analyses is an area's historic service use relative to the national average. We define relative service use for a geographic area as spending adjusted for prices and health status relative to the national average. By removing the effect of prices and health status we get a better measure of relative service use. High service use in an area is a good indicator that there is excess use there that could be reduced by an ACO.

Relative service use has the highest correlation with savings of any of the variables we examined and explains 18 percent of the variation in savings by itself.

It is also correlated with other variables. For example, it is has a positive correlation with the South and a negative correlation with hospital-based and large ACOs.

So to sort out these cross-correlations and see what's driving savings, we turned to a multivariate model.

From the multivariate model, we find that prior service use in the area where the ACO's beneficiaries live is the dominant factor in predicting savings.

The parameter estimate for service use, which is highlighted in green on the chart, is almost 0.2, meaning that ACOs in areas that historically had 10 percent higher service use are expected to have 2 percent greater savings. And this is a statistically significant result.

Other variables had much smaller effects.

The ACO being large, that is, having over 10,000 beneficiaries, is significant and negative, and Southern (as opposed to all other regions) is significant and positive. But these two are of lesser magnitude than service use.

Being primary care or multispecialty based are not significant, which some may find surprising.

To sum up, where you start determines how you finish, which makes sense. If an area has a lot of excess service use to begin with, there is something to reduce. If there was little or no excess service use to begin with, it's difficult to cut it.

Jeff can go into detail about these results on question, but the takeaway is prior service use dominates.

Visually, we can see that result. In this graph we have ACO savings as the Y-axis and relative service use

on the X-axis. If you look at the upper right-hand corner, these are areas that historically had service use 20 percent higher than the national average. This shows that every ACO in Miami, Florida, Hammond, Louisiana, and McAllen and Houston, Texas, made money. None are below zero percent savings.

Conversely, of the ACOs in areas that had service use below 0.9 on the left side of the slide -- that is 10 percent below the national average -- ACOs rarely generated shared savings. And the results, of course, are much more mixed in between.

So at this point I am going to pause and make a brief digression.

In your mailing we mentioned a white paper that researchers at the Harvard Medical School did for us on Part D and ACOs.

Everyone agrees that it would seem to make sense if there were some mutual incentive between ACOs and prescription drug plans to both control drug costs and improve health outcomes. For example, it would be a good thing if physicians in ACOs had some incentive to prescribe generics or if PDPs had a reason to favor drugs that had

good long-term effects on a patient's health.

However, the paper found two problems with doing this.

First, there is a mismatch between beneficiaries in PDPs and ACOs. In ACOs beneficiaries are attributed sometimes not until the end of the year; whereas, beneficiaries enroll in PDPs before the year starts. An ACO can have beneficiaries in multiple PDPs or not in Part D at all, and vice versa for the PDPs, so there is a basic mismatch.

Second, risk sharing is very different. Medicare puts the risk on the PDPs and beneficiaries for drug costs and only retains reinsurance risk, so that is really all that Medicare could share with the ACOs.

The result is they could find no straightforward approach to align incentive between ACOs and PDPs, and we can talk about this more on question.

So back to the findings, in conclusion, we find, as do others, that for the Medicare Shared Savings Program ACOs in 2015, physician-based ACOs (as opposed to hospital-based ACOs) small ACOs, and ACOs in the South tend to show greater savings.

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However, our multivariate analysis finds that the historical service use in the ACO's market area is the key determinant of savings for the ACO.

In addition, CMS reports high quality for ACOs, but they use primarily process measures, and we have raised some concerns about that in the past.

So beyond these finding, assessing the overall performance of the ACO programs faces some challenges.

From the Medicare program perspective, in the case of one-sided models it is difficult to assess. Some ACOs do appear to save money, but Medicare could still lose money overall because it shares savings with the winners and does not collect from the losers.

Also, because the program seems to be around breakeven, it may be important to estimate second-order effects before judging overall success. For example, if providers in an ACO change practice patterns to be more efficient, they may treat their non-ACO fee-for-service patients in the same way, and that could generate savings for those beneficiaries as well. If growth in fee-for-service spending decreased, that in turn could affect benchmarks for the Medicare Advantage program, creating

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further savings.

Meanwhile, from the ACO perspective, they must balance administrative costs -- that is, the ACO's cost of setting up and running the ACO over and above usual practice costs -- against their expected shared savings to determine whether to participate or not. One could consider those additional costs in overall performance.

So MedPAC has set out some policy principles.

First, we have said to synchronize the benchmark in a geographic market across Medicare Advantage, fee-for-service, and ACOs.

Second, for ACOs we have said they should move to two-sided risk to make incentives stronger and assure that Medicare benefits, and that ACOs should be large enough to measure reliably both for spending and quality.

With those principles in mind, our findings raise the following issues:

First, historical benchmarks rebased as ACOs go on are not sustainable, as the MSSP has recognized as it moves to blend historical and regional benchmarks going forward. But what is the endpoint? Should we level the playing field, as the first principle would suggest,

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knowing that ACOs are less likely to achieve savings in areas with a history of low service use and may not enter in those markets? Or perhaps favor two-sided ACOs in low-service-use areas?

ACOs only in high-use markets would save the program money, but could be an issue if ACOs are being counted on to spur delivery system reform.

Second, small ACOs may be more successful, but it is also more difficult to measure their performance accurately, and they may be less likely to want to take on two-sided risk.

So it's possible we could aggregate small ACOs to pool risk and increase measurement accuracy. And the markets are kind of doing this already. Some companies providing the back-office functions for small ACOs, thus decreasing their administrative costs.

We could also limit risk to encourage movement to two-sided models, perhaps harmonizing that with the 5 percent bonus in MACRA.

We look forward to your discussion and your questions. Thank you.

DR. MILLER: Can I just do two quick things by

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one clarification for the Commissioners and one for the public?

For the Commissioners, the reason you had that little pause in there for Part D is a couple of different times people have said, you know, can we have, will we think about this. So, you know, given our workload, we kind of offloaded this and brought it back into the conversation. I am definitely looking at you because I remember you being one of the people.

So there is an issue--oh, no, it's fine. There's an issue there. The complexity of how to solve it I think is what we would need to talk about.

And then to the public, I think everybody on the Commission got it, and you have the benefit of the paper, but let me be clear, David. In the general literature, some people are reaching the conclusion that physician ACOs do better. And I think the point of your analysis is don't jump to that conclusion so quickly. It may have -- the dominant effect may be where they started which would be determining how they're actually performing here. Is that fair?

MR. GLASS: Yeah, that's correct. Jeff, do you

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have --
DR. MILLER: Right, and I just wanted to make sure that that clean --
MR. GLASS: There are a lot of variables. They tend to be correlated. It's easy --
DR. MILLER: And we went through it all very carefully, but I wanted to kind of bring it back down to one sentence for people who might not be as analytically inclined.
DR. CROSSON: Okay. Nice work. We'll do clarifying questions.
MR. GRADISON: Does the length of time that an ACO has been in business have any correlation to the variables you were looking into?
MR. GLASS: A lot of people seem to be reporting that savings is better if you've been in the program longer.
MR. GRADISON: I'm sorry. What [off microphone]?
MR. GLASS: A number of researchers have reported that savings seems to be greater if the ACO has been in the program longer, and one possibility is that the ones who haven't been successful have left, so it seems like a

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greater proportion of the ones remaining are doing better. And it also could be where their bench -- how their benchmark was calculated to begin with because they look back three years, and if those three years happen to be higher. So, yes, a lot of people have found that. I don't know that it's that convincing.
MR. GRADISON: Thank you.
MS. THOMPSON: On that question, is there a corollary to that? Is there a point at which you reach diminishing returns where you've cut costs to the point where there's no longer savings to generate?
MR. GLASS: Well, one interesting thing -- do you want to flip back to the overall financial results? So if you look at the Pioneer versus the -- yeah, that's it. If you look at savings, it's 0.7 for Pioneer, 0.6 for MSSP, which might seem surprising given that you have two-sided risk over on the Pioneer side. Well, this is in 2015, and the Pioneer is -- let's see, it was '12, '13, and '14 was their first three years. They then rebased the benchmark, and when they did that, they looked at the three years they'd been in the Pioneer as the new baseline to create the benchmark. And, yes -- and that's your point, I think,

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and it becomes difficult to save after you've saved for a number of years. So I think that might be why you're seeing this result right here.
In MSSP, they're changing things a bit so that instead of just looking at the historical for that particular ACO, they're blending in a regional factor into the benchmark.
DR. CROSSON: Okay. Let me reboot here for a second because, in terms of hand-raising, up above the head. Okay? Oh, no.
[Laughter.]
DR. CROSSON: All right. So we'll start again with Bruce.
MR. PYENSON: Thank you very much for the terrifically done report.
A couple of questions. You had mentioned perspective versus retrospective, and there's a school of thought that says, which you alluded to, the prospective is better because ACOs have a perspective and can plan to manage individuals, and is there any evidence that it actually makes a difference? is one question.
And my second question is on what I called

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utilization index, which you had a different term for as the geographical basis.
MR. GLASS: Service use.
MR. PYENSON: Service use, yeah.
Is there any -- how does that connect with the viability of MAPD plans, who have a similar perspective of how can they survive financially, how can they reduce utilization? Is that something --
MR. GLASS: I have a simple answer. I have no idea on the MAPD point. I'd have to think about it. We'd have to ask the people who thought about that a little bit.
On the prospective versus retrospective, I don't know. Jeff, have we found evidence one way or the other?
DR. STENSLAND: I don't think there's any good evidence because, basically, everybody is retrospective except for the pioneers, and then you just have a few observations. But you have lots of other differences with the pioneers and the MSSPs. And I think you just have too many moving variables between the two different groups to pin any sort of pioneer versus MSSP, just on the perspective/retrospective aspect.
DR. CROSSON: Having said that, we did hear and

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continue to hear from participants in the ACO program that they have felt historically -- and many still do feel -- that they could do a better job with prospective rather than retrospective. Whether that in fact is the truth is another question.

MR. PYENSON: Yeah. I've heard the same thing, and it's exactly the question: Is there any truth to that or evidence for that?

DR. CROSSON: Kathy.

MS. BUTO: Yeah. I wonder if you could remind us if there are good comparisons of how well ACOs are doing vis-…-vis managing chronic disease or complex patients, since one of the ideas is not just reducing cost vis-…-vis fee-for-service, but coordinating care and improve -- and I know quality measures look pretty good. The question is, Do we have good measures of the management side of what the ACOs are supposed to be doing?

And second question is, on the Part D ACO connection, would there be any possibility for better matching of patients enrolled for the prospective models versus the retrospective? In other words, if at least both have prospectively identified patient populations, is there

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some way that that is better, a better vehicle, although it's a small sample of patients?

MR. GLASS: Right. I mean, they're prospective, but they're not enrolling.

MS. BUTO: Not enrolled.

MR. GLASS: Yeah.

MS. BUTO: Yeah.

MR. GLASS: They may not even be aware that they're prospectively attributed to an ACO or what an ACO is. So there's still that issue, and there's still the problem that they could be in multiple Part D plans or not have Part D at all. So I don't think it helps too much.

DR. CROSSON: Bill Gradison.

MS. BUTO: Well, wait. Can I get --

DR. CROSSON: Sorry. Kathy.

MS. BUTO: The question about the coordinated -- the management of patients, any better sense of that?

DR. STENSLAND: I don't think we had the data right now that are lined up well enough to determine that. I think we hear a lot of stories of people thinking they're doing good things, but when we look at the savings, we see a lot of the savings coming from things like reducing post-

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acute care costs, which were highly variable.

We don't see this huge amount of savings of, okay, all of a sudden, our ED visits have gone way down or our admissions have gone way down or those kind of things that maybe there's some programs that can say they've done it, but systematically, we don't have any really clear evidence that says, oh, you know, this is now our example where care management is really working great.

MS. BUTO: Just to comment that since other work we've done, we look at ambulatory sensitive conditions and so on. You would think that would be something that could be tracked, and maybe it is being tracked.

MR. GLASS: Well, next month, I think we're going to say something about that.

DR. CROSSON: Bill.

MR. GRADISON: Is there any evidence whether MSPs that have produced savings have resulted in lower Medicare spending and the rest of fee-for-service in their geographic areas?

MR. GLASS: The spillover question. Jeff?

MR. GRADISON: The spillover. I mean, I've heard, seen things written about that --

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MR. GLASS: Yeah.

MR. GRADISON: -- with regard to MA, but I haven't personally seen anything about the ACOs.

DR. STENSLAND: I think we're in the same place. People certainly hypothesized that that's going to take place, and there obviously have been some papers suggesting there's some data on the MA side. But we don't have clear data on the MSSP side.

DR. CROSSON: And it's entirely possible this is a timing issue. I mean, MA has been around for a lot longer than ACOs, but particularly successful ACOs. So I don't know how long one would assume it takes for that trickle-down effect or whatever you want to call it to take place, but it might take place, but it might take some time.

DR. MILLER: And I would also draw this distinction in your mind. One of the things that David's slide on the savings relative to benchmark versus how you dispose of the dollars, so you can have .5 percent in savings, but to the extent that you give it back without taking any losses, then you're actually on net, putting money back into the stream. And remember a secondary

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effect of that is that it links to the MA baseline.
I don't know of any evidence that's showing a spillover, but let's say you got a spillover from the savings effect, remember what you do with the money can be recycled back into fee-for-service and recycled back into MA, so --
DR. CROSSON: Great. Bill Hall.
DR. HALL: The idea of looking for super performers is always kind of interesting, and the issue about the South doing a little bit better, do you have any speculations on that?
MR. GLASS: Well, what the evidence shows is that it's because of service use there was incredibly high.
DR. HALL: Right. And nothing beyond that, the service use by vendors --
DR. CROSSON: Craig.
DR. SAMITT: So great report. Thanks, and thanks for humoring us in terms of the Part D analysis as well. I'll come back to that in Round 2.
Slide 10. I had a question about the multivariate analysis because the finding that confused me was the small versus large ACO that you commented on in the

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reading materials. But one of the correlations you didn't comment on, for example, was the high correlation between large ACOs and hospital ACOs, and so then I began to wonder how much have we teased this apart.
Are small ACOs predominantly physician ACOs, which are predominantly in the South, and is this really all just about prior service use, without any other determinations that could be drawn? Or are there confounding variables here? You know, it is not small versus large; it's hospital versus physician. I had a hard time really teasing that apart to see what the truth was, so --
DR. STENSLAND: So I think that's kind of this purpose of this multivariate analysis is when you look at it, they say, well, there's lots of different groups that are doing better, small physicians, South. So what is really driving that? And so we put all the different variables in this multivariate model and kind of make them all fighting it out and see where the power of explanation goes to.
And I think the historical service use comes out as dominant, and once you enter that in, basically whether

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you're a physician-run ACO or a multispecialty-practice ACO, that kind of goes away.
So what does still show up, to some degree, though, a fairly small degree, is that the smaller ones do better, but there could be a couple of reasons for this. One reason could be that, oh, you're just small, and it's easier to manage a small group of physicians; you can keep them all on the same page. Another aspect could just be the incentives. Whether you're a small physician ACO or a small physician hospital ACO, if your pool of the total share of dollars is a small share of it and a lot of it is leaking out, you have a bigger incentive to reduce all that stuff that's leaking out. So the incentives are actually different too.
But the summary idea is when we looked at the multivariate analysis, we think whether you're a physician or non-physician kind of goes away being small. It still has a little bit of an effect. Being Southern, for some reason, still has a little bit of a positive effect, but it's barely statistically significant. So I wouldn't put too much emphasis on that.
And the main thing is, if you had a whole lot of

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extra use, you have something to cut.
DR. CHRISTIANSON: Jeff, maybe what Craig is asking, in a way, is, Did you fool around with any interaction effects in your modeling?
DR. STENSLAND: Yeah. We had various interaction effects, and those didn't really play out as being the explanatory factor. Like if you're small and a hospital or if you're a physician only in small, that's not really what's driving it. It was kind of surprising, actually, to us to see, okay, some of these smaller ones that have physicians and hospitals in them tended to do a little bit better than expected, just given their service use.
DR. CROSSON: Sue.
MS. THOMPSON: In the discussion regarding service use versus benchmarks, talk to us a little bit more about adjusting by HCC scores, and the focus of my question is around some areas of the country who don't have population where Medicare Advantage has taken effect haven't much track record in HCC scores. So help us think about how you crosswalk from benchmarks to service use, particularly for those areas.
DR. STENSLAND: So I'll start with, you know, the

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standard story you'll often hear is somebody will say, "Well, that ACO has a benchmark of $14,000. Of course, they can generate some savings." But the question is, Is that $14,000 benchmark high because prices are high like they are in San Francisco, or is it high because their people are really sick? If it's one of those two things, they're not going to have much chance to adjust it, to reduce.

So we wanted to convert it into service use, and that is the story such as, okay, you're in Houston, and in Houston, even adjusting for prices and the comorbidities of the patients, people are getting 25 percent more care than we would expect -- or they used to get 25 percent more care than we expect, so we expect you to generate some savings. And, lo and behold, they did.

Now, there is the question of our -- this gets a little bit technical, but the question of are people coding equally across the country -- and so, certainly, if you're coding a little heavier in some places like Florida -- Miami has their reputation for maybe coding a little heavier, and in some other parts of the country, maybe you were coding lighter. So there could be some effect there,

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and to the extent that that's going on, we would probably be actually underestimating the effect of service use a little bit.

But we did try to do some -- the way we adjusted for service use, it gets technical, but we tried to adjust it a little bit like that. We just didn't divide by the HCC score. We put in some dummy variables for the different markets, which helps us from over-adjusting for the HCC score.

So I think if you look at our method versus some others, we'll be a little bit, in essence, giving Miami a little bit less credit for their high HCC score than some other people do. I hope that helped.

DR. CROSSON: Clarifying questions. Jon.

DR. CHRISTIANSON: David, the last slide, last bullet point, could you just expand on that a little bit, please.

MR. GLASS: So this is the question of could limit risk to encourage two-sided and harmonize with APM 5 percent bonus. So that is pretty cryptic.

[Laughter.]

DR. CHRISTIANSON: Thank you.

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MR. GLASS: So it has a couple ideas packed in there. One is that -- this is particularly for -- say you're a small ACO. They may be very reluctant to take on two-sided risk, particularly say you have a primary care-based, small physician-only ACO. They are actually only -- their share of Medicare spending, what they get is fee-for-service revenue. It is probably only 5 to 6 percent. So putting them at risk for the 100 percent of total fee-for-service spending may seem particularly onerous to them.

And so this is as thought about, well, so maybe you tailor the amount of -- you know, the maximum amount of risk they can take to something perhaps approximating their fee-for-service revenue or some function of their fee-for-service revenue, and then there's this question of the APM 5 percent bonus floating around. And that could -- if that's limited to two-sided, that could be a further inducement to go into a two-sided risk.

DR. MILLER: Just to make a process point -- and we probably should have said this a little more at the setup. So there's a two-step process here. The purpose of today's session was to kind of set the table -- here's the results, here's what we're seeing out there, that type of

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thing -- because there were some statements made in other meetings about looking back at the risk structure in the ACO world to address issues like small ACOs and that type of thing. So the idea is to stage that conversation following it and to begin to really unpack ideas like this and put them in front of you. It's fine for you to do what you're doing here, but that's the setup for where we're headed.

DR. CHRISTIANSON: Yeah. I didn't understand the "harmonize with the 5 percent bonus" part.

MR. GLASS: So that's the extent of our thinking so far on that.

DR. CROSSON: Brian.

DR. DeBUSK: Bringing us back to the South for just a moment, I understand that the Southern ACOs perform better, but something that stands out on Chart 9 -- and if you could speak to this, I'd appreciate it -- it would also appear that there are more ACOs in the South and that they are by a ratio of 2:1 more physician-led.

So my first question is -- I mean, it sort of looks like there's something here that maybe they know that we don't know, and if you could speak to that, I realize

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these variables, there's a huge causality issue here. But you've had the benefit of playing with the data, so I'd really appreciate your input.

And then my second question is, Do we have a feel for how service use and the pricing of those services correlate to ACO success? For example, have we looked at something like maybe the wage index? Would the wage index in a particular region be a predictor of ACO success? Because in theory, it shouldn't, because it should be transparent. But have we explored the idea that maybe some of these services are used in higher amounts because they're underpriced or mispriced?

MR. GLASS: Well, that's a question of whether the wage index is defined appropriately, I guess, and we've actually opined on that in the past, though it's been many years ago, about better ways of doing the wage index. So there could conceivably be some effect there.

Here, we're essentially -- the service use essentially removes the wage index from the --

DR. DeBUSK: It would be interesting if you looked at ACO success to see if the wage index itself would be a predictor because, again, in theory, it shouldn't have

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any predictive value.

MR. GLASS: Yeah, that's true.

And as far as it would be -- it seems entirely rational for a lot of ACOs to be set up in places where they might succeed. So I think, yeah, maybe they do know something we don't know -- or that we perhaps to know -- that you should set up someplace where you have a good chance of success in those places or those with high service use.

DR. STENSLAND: And I think we were actually surprised at how few there were in the South. Like in the first couple rounds, we thought, oh, my gosh, people are just going to be lining up in Miami to start doing this because we have all this extra service use -- or in McAllen. And, in the first year, they really weren't all lining up, but now we see -- after a couple of years, you see more and more movement to the South. And I think part of that is they kind of caught on that, oh, okay, the savings are going to be easier down here.

DR. DeBUSK: So they're moving where the money is.

DR. STENSLAND: Yeah. It's stupid.

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DR. CROSSON: Funny about that. Okay. Alice.

DR. COOMBS: So Slide 7, we're making an assumption that the spend per beneficiary is exactly the same in these two -- the Pioneer and the MSSP. I mean, I don't see numbers, the denominator for the aggregate cost.

MR. GLASS: Oh, you want a calculation of what the benchmark per capita is in the two programs?

DR. COOMBS: Right, right.

MR. GLASS: We can do that.

DR. COOMBS: Well, the problem I see right now is that you look at the benchmark, you look at the actual spending, and you look at the savings. What I'm interested in is how is the spend per beneficiary, comparatively speaking, between the two. And I don't know if you can do that, but that would be something that I would be interested in.

MR. GLASS: We can give you the average benchmark in each of the programs.

DR. COOMBS: Okay. Because they're not equal, right? The two columns are different.

MR. GLASS: It's easy to calculate, and we can give you the number.

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I mean, I can tell you, though, that it will depend on the fact that a lot of -- for instance, a lot of the Pioneers are in Boston, and they're going to have the higher, you know, spend.

DR. COOMBS: Which leads me to the next question.

[Laughter.]

MR. GLASS: That's one of the reasons we move away from this when we look at it.

DR. COOMBS: I was going to say in slide -- go back to the slide we just had, Slide No. 9. So Craig said something, and I'm thinking along these lines, that there's some confounding variables here. And if you were to regress and take out the South and look at the Northeast, you probably would find large ACOs, hospital-centric, and you'd have probably a larger degree of consolidation within the area. There was a journal article in the New England Journal that talked about physician-led ACOs versus hospital-led ACOs.

And what may be at work here is the actual 5 percent cost of increased health care spending in areas where there's a lot more consolidation. So I'm wondering if that's a factor for the ACO success.

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And then I think we've talked about this several times over the years. Lastly, have we looked at the Pioneer dropouts, the ones that didn't graduate, to see what their rate-limiting step was for their failure?

MR. GLASS: Well, I think some of them wouldn't say it's a failure because they moved to the NextGen model.

DR. COOMBS: Right, but not all of them moved --

MR. GLASS: And some of them moved to MSSP.

DR. COOMBS: Right, whichever -- so NextGen I would think would be comparable, but for the MSSP conversions, what would -- would it be just purely the risk and the costs being prohibitive?

MR. GLASS: Well, it could also be that they get a different benchmark. If the calculation of the benchmark is from a different period and a different way of doing it, they may just have felt they'd get a much more favorable benchmark in one than the other, which would be perfectly rational, and they might have switched for that reason.

DR. COOMBS: And is it something about the risk adjustment and how it's done in the different entities in terms of over what period of time the risk adjustment is looked at?

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MR. GLASS: The risk adjustment is very -- that's a very complicated question, and I don't really know the answer to how they would assess whether they'd be better off in one program or the other because of the risk adjustment. I think the risk adjustment is kind of moving toward each other. Actually, I think the Pioneer switched to look more like MSSP, or the other way around. Do you remember which it was, Jeff? I think it was they switched to look more like the MSSP. But that gets very complicated, and I don't know that even the ACOs would be able to model how that was going to work.

DR. CROSSON: Pat, on this point?

MS. WANG: Not really on this point.

DR. CROSSON: Oh. Did I miss you?

MS. WANG: No. No, I'm just --

[Laughter.]

MS. WANG: I just want to get into the queue. That's all.

DR. CROSSON: All right.

DR. HOADLEY: So two questions, one of which has already partly come up. One, on Slide 5, you mentioned some of these new payment approaches, the population-based

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and the partial capitation. Do we have any information on how many -- or whether there has been much takeup on those alternatives? Or is it -- do we have information on that?

MS. McCLENDON: At least in respect to the Pioneer ACOs, we had three over the course of the years that they've been able to select this go to the population-based payment. So we still see the majority taking the fee-for-service track. I don't know that we necessarily have the numbers yet on NextGen as to which payment track they've chosen.

DR. HOADLEY: It would just be interesting to know whether -- is this one of those things where it's out there but nobody really ends up interested in it, or --

MR. GLASS: This is the first year for Next Generation, and some of these I don't think are available in the first year.

MS. McCLENDON: Yeah.

DR. HOADLEY: Okay. So maybe that's a question for the future.

And then the second actually picks up from where Alice was, which is the dropouts, and not just the dropouts from Pioneer, but I think you talked about a fair number of

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dropouts out of MSSP. And I think at some point in the past you looked at some of the early dropouts, but, you know, it seems to me that they're -- I don't know if there's been any literature looking at this or anything you've looked at, but it seems to me they could be responding to a variety of factors, including sort of designed benchmark kinds of things that you were just alluding to, a basic failure, organizational failure, they just couldn't figure out how to do it, how to change practice patterns in a way to get a response. Or they could be pure financial decisions. We did not make money, we didn't have any savings to share, whatever. And I don't know if there's been any literature yet, or if it is, again, too early to sort of have the experience to do that.

DR. STENSLAND: I think the last one is the dominant. If you look who drops out, it's they didn't make money. If you made money, even if you don't know why, you stay in.

DR. NERENZ: Thanks. This is really good. Two quick things.

On Slide 7, please, bottom right-hand corner, I just want to confirm something that Mark said. The

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negative sign there means that in 2015 the Shared Savings Program cost the Medicare program money. That's what that means.

MR. GLASS: Right. We're now looking at any second-order effects.

DR. NERENZ: I understand. I understand. It's not big. But we don't hear that very much, but I just -- okay.

And also, Slide 13 -- and, David, you were pointing to the upper right quadrant, and you used the term "made money." I just want to clarify. What they did in the upper right quadrant, they generated shared savings, but we don't know if they made money.

MR. GLASS: They beat their benchmark.

DR. NERENZ: I understand, but that's not the same--

MR. GLASS: That's all we can say, because some -- if it's really close, they didn't even share savings. If it's within 2 percent, they don't even share savings.

DR. NERENZ: Exactly my point. We don't know if they made money unless we know their operating costs.

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MR. GLASS: Right.

DR. NERENZ: Okay. The language is important because I think later the concept of "made money" that we just had here is important, and I just want to point out that's not reflected up there.

MR. GLASS: Okay.

DR. NERENZ: Thank you.

DR. REDBERG: Thanks for an excellent chapter, and I think actually my question follows on David's last comment because I wanted to get at, I guess, operating cost. Is that in the actual spending number? Like what you had to do to start the ACO.

MR. GLASS: No.

DR. REDBERG: So that's not there at all?

MR. GLASS: No, that's not there, because that's -- I mean, the ACO has to make that consideration: Does it want to be in this game or not? It does not show up in this.

DR. REDBERG: But I'm interested if we have any data on how much those costs were and how much they varied.

MR. GLASS: It's kind of --

DR. REDBERG: And were they related to predicting

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savings? Like if you had a bigger, you know, infrastructure, did you do better? Because those I assume would be fixed costs, and then these would all be variable, or somewhat.

DR. STENSLAND: We don't have data on all the individual ACOs' internal costs of operation, and sometimes when we talk to them, they're not exactly sure either what their internal costs of operation are, because, you know, oh, we have some people, they work part-time on the ACO, they work part-time on something else. But the National Association, when they do surveys, it used to be a little higher, but now it's getting down toward around 1 percent, and sometimes a little over 1 percent. Some people have told us under 1 percent. You know, there's a lot of variation there.

DR. REDBERG: One percent of their total budget?

DR. STENSLAND: One percent of the beneficiaries' annual cost of care. So then, you know, if you would have to basically generate 2 percent savings, according to CMS metrics, so that then you would get half of that, or 1 percent, it would then pay back your overhead costs. But if you do look at this slide, almost everybody's savings in

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that quadrant are, you know, way over the 2 percent marker. So most of that people are going to actually be able to make enough money to cover their administrative costs. But certainly if you are close, if you are more like the people in the middle, it's important.

MR. GLASS: The other interesting thing is the market is kind of -- this may not be a clarifying answer. The market is kind of moving into this space and providing the back-order analytics -- back-room analytics for ACOs. So there are companies that will -- your ACO doesn't have to set up an analytic shop to figure out all the data and figure out what they're doing. There's actually companies now that will do that for you. So it could be as time goes on the administrative costs will drop because these other companies will get into it and it will become a commodity.

DR. REDBERG: Thank you.

MS. WANG: On Slide 16, can you share more of your thinking about the possible issues one and two, historical benchmark, not sustainable, blend with regional average. What is the region, what does that mean, and how that relates to the second bullet, leveling the playing field? What are you thinking?

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MR. GLASS: So the historical benchmark, not the -- well, this is the question of after three years in an ACO program, your baseline is recalculated to become your new benchmark, and it uses your last three years of experience. And if you've been in the ACO program and diligently, you know, working away to reduce service use --

MS. WANG: [off microphone].

MR. GLASS: Right, it's going to be pretty low, and it may be difficult to achieve further savings. So the way the MSSP program is now doing it -- and they hadn't done this in the past. I'm not sure which year it starts. But they're going to recalculate -- when they recalculate the benchmark after the first three years, they're going to factor in -- and I forget what percentage it is exactly -- regional spending. So if you're in, say, Houston and the regional spending is an average of 10,000 a year and your ACO has worked down to 9,000, and if you average your last three years, you would have had a 9,000 benchmark, they're going to factor -- they're going to blend those two together. So say they've blended 50-50, 9,500 would be your new benchmark.

MS. WANG: And just to clarify, the region is

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defined as?

MR. GLASS: The counties where your beneficiaries live.

MS. WANG: Okay, county specific --

MR. GLASS: Weighted by the number of beneficiaries in each county, I believe.

MS. WANG: And so your second bullet in low-use markets, do you have thoughts about how you would level the playing field across these programs? Because in low-use markets, in theory anyway, the MA benchmarks would be, let's say, above 100 percent. Would you -- I mean, that's not scientific, but it exists, right? What would you do? Do you have --

MR. GLASS: Yeah, so, I mean, that would be one way of doing it, would be to, you know, mimic something like in the MA program where -- they're doing it on spending. I think we'd prefer to do it on service use rather than spending. But you could mimic something like that and give them some advantage for being there.

Now, again, the Medicare program saves money when you set up an ACO in a high-service-use area and reduce service use. If an area already has low service use, it's

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not clear Medicare program saves by having people in ACOs, but maybe you do it for some other reason. But that's what the Commission would have to think through.

DR. MILLER: Right, and I think, you know, this starts to segue into bigger questions, and maybe the timing is right, if we've done the clarifying. There's always this instinct, and you saw it in MA and you're going to see it here, and I think as a Commission you're going to have to grapple with it, which is, okay, you know, if you do a historical benchmark and you bring it down, then you've maxed out. So what do you do at that point? And you also have MA and fee-for-service if you're thinking about the market, you know, broadly. There will be lots of instincts of, like, well, okay, we'll adjust the benchmark up so that they still have some headroom; or if you're in a high-cost area, adjust the benchmark down, you know, that type of thing, you know, that people will want to tinker with it to support a given model. And, you know, the Congress has done that, and those are reasonable thought processes.

But the other question is if you are going to be thinking about fee-for-service and MA and ACOs from a payment policy point of view, are you going to have

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different standards for each one of them? Are you going to be adjusting to try and promote different things in different markets? And at what point do you have, you know, a system that has a lot of arbitrage opportunity, for lack of a better word, anyway?

And so a question when we come back and start talking -- and we can start it today and talk about what to do about setting risk. That will be an inherent tension around all of this because a lot of people will say, well, I want to create an environment where people are willing to take risk, which generally means giving them headroom. But then you're sort of tinkering with this.

And so a question you'll eventually have to come back to or starting today is: How do you want to think of those marketplaces? And a real raw way to say it is you set a benchmark -- and let's just assume we all know what that means for the moment. That's complicated in and of itself, like service use or dollars. And then you let the chips fall where they may. Or do you have these adjustments in order to, you know, try and bring people into models? I think that will be an inherent tension that runs through all of your conversations. And I think that's

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an -- what did you say? -- oblique way to try and say that. It wasn't intentionally oblique.

DR. CROSSON: Okay. Seeing no more hands, we'll start the general discussion, and Paul is going to kick off.

DR. GINSBURG: Thanks. First, I wanted to really praise the staff on bringing in the area service use variable, and particularly for using a multivariate analysis. You know, there are so many -- you've really just, you know, shown another instance of where a straight descriptive analysis is potentially very misleading. And at the Center for Studying Health System Change, we put out a lot of descriptive information. Initially, what we would do is we would only publish it if we had -- considering the audience, if we had done a multivariate analysis and they had stood up. If they didn't stand up, then we wouldn't publish it as a descriptive thing.

Then we got more sophisticated and started just doing regression-adjusted means and publishing them, and that really solved the problem. So, really, you know, besides praising the staff, talking to the broader fields, you know, we need to get our act together when we deal with

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descriptive data, because I'm concerned about all the misleading results that are out there that your analysis showed really didn't have much behind them.

So then I had a thought about the two-sided risk, which is that for physician-led ACOs, I mean, I think that to get them to take two-sided risk for this entire thing is not realistic. In California, where there was all this success with the delegated model, the IPAs and multispecialty groups that are at risk, never took risk for hospital care. They didn't even want to take risk for prescription drugs once those prices started becoming less predictable. And I think that with CMS having long tried to be supportive of physician-led ACOs, they could develop -- and we could suggest -- a two-sided risk model for physicians that was lower risk on both sides, both the upside and the downside. We don't want to reduce -- limit the risk to just physician spending because, you know, some of the data I've seen shows that they tend to spend more on primary care services and they save it in hospitals. So you want them at risk for the entire body of services, but maybe it just needs to be scaled down in those cases.

And, finally, I had some thoughts about Part D,

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the digression, and I'm a little bit more optimistic about the potential for bringing Part D into ACO calculations. And it's not based on having studied it for a while, but it's more based on, after I read your material, I said, well, how might I do it? And the notion I would do it is that, first of all, I wouldn't bother with sharing savings or losses with either the Part D plans or the beneficiaries who enroll in them. And all I would do is that for the beneficiaries attributed to an ACO, I would go and find out what their Part D spending is from the plan. And, you know, if the plan gains or losses, Medicare's going to get it back in a future round of benchmark settings for Part D.

But you mentioned the incentives to use less expensive drugs. I'm also concerned with what we've heard from the pharmaceutical companies for years about greater use of drugs can have significant offsets in Parts A and B. And, you know, given what many of the ACOs are doing to foster better care management, that probably does include, you know, better management of diabetics may mean more Part D drug use.

So in a sense it's something that could almost -- you could actually be imposing higher costs on the Part D

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plans, but ultimately that will be resolved, and this way the ACO can actually get some credit or shared savings if they actually use drugs in a more effective way and actually do save Parts A and B in the process.

DR. CROSSON: Just to comment, Paul, to agree with you on the notion that -- and I guess this is not MedPAC policy as much as it is -- well, maybe it is. But to the extent that the breadth of risk can be expanded, you know, in other words, the ACO. and even at the level of the individual physicians, has an understanding that it really is accountable for the entire spend dollar, that's a good thing. But that's a separate issue from how much risk -- what percentage of whatever measure you want to use, income or whatever, is at any given time in the evolution of an ACO at risk and how much gain and how much loss is likely to take place and what degree and what different sorts of risk-sharing arrangements could, in fact, be constructed for CMS while the breadth is being expanded I think is a key point as well.

Let's see hands. We've got a fair number of hands, so I'm going to start over here and go this way. Brian.

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DR. DeBUSK: First of all, I'll say these ACO results are fascinating because I do think there's a message in the data, and I do want to applaud the staff on the development of this service use measurement. I think it was very novel.

But it addresses the analytics. I mean, it helps us sort through the data, but it doesn't address the underlying issue of selection by, and skewing, who chooses to participate in the ACO, and I think that's going to come back to the benchmark.

So as I was reading the summary, leading up to this meeting, there was this inescapable feeling that we're going to have to circle back and address the benchmark, because I think until we get that right, even though we can develop the analytics to see through the problem, what we're going to continue to do is skew the people who choose to participate in these types of programs.

The other thing I'd like to point out, I think the South is a really interesting laboratory, because it gives us an opportunity to address the relationship between the service use and the pricing of those services. I just -- I find it hard to believe that the South just simply

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uses more, because. And I'd like to explore this idea that maybe what we've done is mispriced or undervalued some of those services, at least in select markets, and they're making up the difference on volume. And I'm not quite sure exactly how to get to that but it would be nice to see the relationship there between the service use and the service price.

Thank you.

DR. CROSSON: Alice.

DR. COOMBS: Thank you very much, and any good report generates more questions.

[Laughter.]

DR. COOMBS: So I thank you.

First of all I want to speak to the physician-led ACOs versus hospital-led ACOs. I think most of us have an understanding of some of the nuances that happen in the grassroots level in terms of hospital-based ACOs and the need to support the infrastructure of a large institution.

That being said, there are also some environments where consolidation has taken a preeminent role, and, therefore, this consolidation, in and of itself, may drive some of the health care spending.

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I would say that we have an opportunity to consider the clinicians -- the doctors and the nurse practitioners and PAs -- who are in the trenches, in that there is something occurring in the culture. If we can embellish that in any way to support ACOs being led by the clinicians, that drives the culture of quality and also drives the culture of, you know, consideration in terms of cost containment and how, you know, evidence-based guidelines are implemented.

And recently I spoke to some physicians and one of the issues they had was that when they're on a ticker and a time limitation, they feel that there's a reluctance to really take the time that's necessary to kind of sort out some of the symptomatology and chronic disease management, and they may be more apt to order tests that are not necessary.

So that being said, ACOs are supposed to provide an environment whereby they can do what they do best in the office, and that is to really take histories and examine patients, and I think that the ACO should be that kind of environment where it happens, and that there's less tendency to order unnecessary tests.

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This is where the rubber meets the road, in terms of cost and spending. I mean, I could take a history and all of a sudden decide that, no, I'm not going to get a CT scan because I've taken an adequate history, and it changes the whole paradigm of the discussion when it comes to health care spending.

So I don't want us to forget that there's something that happens, the chemistry that happens in the office, that changes the bottom dollar, and for us to really consider that in the discussion of, you know, the cultural factors that happens because we enhance the delivery of health care by the clinicians.

So the other piece of it is, I agree about the benchmark but I also think that one issue is a risk adjustment and how we look at risk adjustment, because that really kind of deciphers those little incremental changes that we're talking about, in terms of how you consider yourself in terms of the bottom spend dollar. That's really important.

What happens in the South is really -- it's understood, by what you've explained in the chapter. What happens in the Northeast, I think it's explained a lot by

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the consolidation. And it would be interesting to take someone from New Orleans and put them in Wisconsin and see how they would fare. But I think a lot of it is explained by the socioeconomic situations that are prevailing, as well as the economic situations that are prevailing in high urban areas where there are lot of academic centers and there's lots of consolidation.

DR. CROSSON: And then there's the question of how they would like the food.

Jack.

DR. HOADLEY: So, again, thank you for this paper. It's really, I think, thought-provoking, and I certainly take the point and agree that, you know, we need to think more about sort of the service use and the benchmarking and some of that.

I wanted to focus, however, on two points. One is, actually, kind of picks up on what Alice was talking about. It seems to me one of the questions is, what's really going on in these organizations to make them work where they do work? You know, is it simply that if you focus on an area that's high use and you just sort of don't really do much of anything, there's a good chance you can

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have a little bit of an impact, or are we really seeing this kind of culture change, organizational dynamics? And I don't know if anybody's sort of done looks inside successful -- I know some years ago you all did some interviewing of some of the ACOs, and I don't know if there's a plan to sort of do any more of that, or if anybody else has done that.

But, you know, I'm just interested in, you know, what is it, you know, how does risk translate into the kind of messages that -- and how might that be different in a bigger or smaller organization. How does it translate into the kind of messages that go out to the individual providers? Do they, you know, hear something about how the risk is going to be reflected in their own incomes? Do they -- is it more of a, you know, kind of integrated approach? And you can see that, you know, within a smaller organization where there could be that kind of dynamic. In a larger organization, you know, have they come up with other ways to sort of organize?

So I think getting some sense of what's going on dynamically in the organizations, particularly the ones that have succeeded and shown something would be helpful,

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and maybe gives us a sense, then, of feedback to how important the benchmarks play and sort of are we expecting different behaviors in a high-use area versus a low-use area, or is this something we ought to be able to -- I mean, if there really is an attention to dynamics, they ought to be able to do something in a low -- in low service use area as well, to make a difference, to eliminate. We know there's lots of unnecessary care sort of in all areas. So it just seems to me that's a useful direction.

The other area I wanted to comment on is on the Part D savings, and like Paul, I think there -- I mean, I completely agree that the conclusion, there's no straightforward approach to the sort of broad thing of linking in because of the nature of enrollment and the nature of the risk structure. But I do think there are some intermediate steps.

And I would mention the CMS request for information, the RFI that was out a couple of years ago, and I took a quick look at the summary document that they have online -- CMS has online, with all the comments, and there are a lot of ideas in there. I didn't have any time to actually go through and sort into them in any way. But,

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you know, I think -- and again, Paul brought some of this up -- you know, some kind of data-sharing. We've already, you know, heard discussion of CMS, thinking about what's the right kind of data-sharing between PDPs, and that's more on the question of their getting data on the A/B use of their drug plan enrollees. But it seems like there's a natural counterpart of, you know, should there be access to some data for these ACOs, in terms of the drug use of their people.

And again, you can think about, so what should they be doing with that? Obviously there are cases where more drug use is going to mean better care. There are other cases where cutting back on unnecessary drug use both could have downstream effects but also just an effect on the drug span.

So even if it just starts with some information-sharing, but I think there are probably other kinds of ways that, you know, more attention to the prescribing behavior and needing that information, even given the sort of fundamental disconnect in terms of the Part D plan model and how it -- the lack of, as, the word used, straightforward approach, to sort of truly linking those

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up. So something that I think maybe we can continue to noodle on, even if it's mostly as a digression and not as the core of what we're looking at.

DR. CROSSON: David.

DR. NERENZ: Thanks. Just two thoughts, now, on the policy side, I guess speaking to the last slide.

In a lot of our discussions, aside from this particular session today, I think we've said things about it being desirable from the beneficiary perspective, that there be choice between traditional fee-for-service, ACO, MA, essentially everywhere. And if we haven't said that quite explicitly, we've often taken, as a premise, that that situation exists. So, for example, tomorrow one of our sessions talks about situations in which you've got those three things present in markets, and then we talked about the dynamics.

Now what I've heard this morning suggests that that may not be how we envision the future, that -- particularly in the ACOs -- that ACOs in certain areas can be beneficial to the program because they generate savings, and they can also make some money themselves because they generate enough savings to cover their operating costs.

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But that's absolutely not true everywhere, and it may be that we decide that the ACO model is a desirable thing somewhere, but it is not necessarily desirable everywhere, and that that's how we think about this.

Now I guess I'd observe that that end point, meaning they exist somewhere, doesn't really require policy change because it's probably going to happen anyway. If you have to have greater shared savings payment than you have operating costs, that will occur, by my calculation, in about a quarter to a third of the ACOs that currently exist. The rest are losing money, and they probably won't lose money forever, and so they will remain in places where they're providing value to the program, and they will fold and fail elsewhere, and maybe that's fine, but at least we ought to think about it that way, I think.

And -- but if we want ACOs to be everywhere, then we really have to think about how some of these current factors have to be changed, because that's not the environment that we currently have.

Okay. So second point, then. It relates to the second bullet here, and I agree to the -- favoring moving to two-sided models. As a just pure general principle I

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think that's fine and I've agreed with that. But given everything we've heard this morning, I have no idea how that's ever going to happen. ACOs -- the majority of ACOs, by everything we've seen, are losing money now in one-sided models. They can't cover their operating costs with shared savings payments. How in the world they would be attracted to two-sided models escapes me.

So again, if we think this is desirable, I think we have to do some creative thought about how that's going to happen, because it doesn't -- it seems unlikely now.

Thanks.

DR. CROSSON: Yeah. Oh. I was going to make -- probably going to make the --

DR. MILLER: Might be reaction to the same.

DR. CROSSON: Yeah. I agreed with the end part of your discussion, with respect to -- or the end part of the first part of the discussion, and that is essentially that in a given area, if a certain model doesn't work, you know, with the payment system and a set incentives that exist, then that's what's going to happen.

I'm not sure I completely agreed that our intention, as a Commission, or our policy is that each one

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of these three models ought to be present everywhere. I think what we have said is that to the extent it's possible -- and it's very complicated -- we'd like to have a relatively level playing field created, with respect to the choices made by beneficiaries, and then allow, you know, some sort of market phenomenon to take place, and to the extent that models either succeed, or ACOs, or MA, or fee-for-service succeeds, or doesn't, then that's the way it is. So --

DR. NERENZ: That's okay, and I fully accept that. I probably tried to exaggerate a bit to get an issue on the table and make the point. But I would accept that that's a better statement of it.

DR. CROSSON: Okay.

DR. MILLER: It is what I was going to address, and the only, you know, adjustment or different way of expressing it -- it's the same point. I think the Commission supports choice, but not necessarily at any cost, and that kind of gets you to the second part of your comment which is, well -- and we went through, and I think Jeff was leading the analysis at that point in time, and actually showed how market-by-market, you know, MAs versus

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ACO versus fee-for-service, you had very different outcomes. And at that time, it was very much along the lines -- at the end of your comment you were saying where it was like, well, maybe all these models don't exist in all of these markets.

Thank you.

DR. CROSSON: Okay. We are going down this way and then we're coming up to Bruce.

MR. PYENSON: Well, thank you very much. I've got a few requests and questions. Mark and David, you both used the term "maxing out on savings," and that's a concept that's unusual in the context of continuous quality control and other industrial engineering concepts. I've certainly heard it -- I've heard maxing out back in the 1990s, with hospital admissions. So if we're going to use that concept I'd like to see some description on whether we think that's a real idea or not, rather than assuming that it is.

Another concept in the success or failure of ACOs from a business standpoint is what -- what's an acceptable failure rate. We should not be -- except that, I think, that all ACOs are going to succeed, and it's certainly the case that that hasn't been the case with Medicare Advantage

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plans or exchange plans or others. So what's our tolerance for success there?

On the Part D issue, I think a reference to the CBO study, that was concerned with generic dispensing, and pointed out that if generic dispensing is hurt by increases in copays that would have a negative effect on Parts A and B. So a natural link might be a connection of a generic dispensing rate for ACO attributed members as an outcomes or quality metric.

And finally, I think the analysis you did, which is superb, is a stochastic analysis. It's a thermodynamic analysis in the sense that geographic is not destiny. So the -- I think you can find, in the cloud diagram, outliers were doing very well who aren't in the South, and organizations in the South who are doing very poorly. And I think that's important because the key determinant, I think, that underlines ACO is the ability of management in an organization to become operationally successful, and that's probably much more important than the other determinants. So identifying those outliers as compared to thermodynamics is destiny, I think is important.

DR. CROSSON: Kathy.

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MS. BUTO: So this work has really been very thought-provoking, I have to say. It's not only the service use issue but I think generally it's caused me to think about what is the point of the MSSP ACO. And I understand that it's saving modest amounts of money, and there are many, many of them, but because of the one-sided risk arrangement it's costing the government money, and I don't see any possibility that's going to change.

So if it's costing more money, and it's not clear whether some of the other benefits -- and maybe we'll get greater clarity -- like better management of patients and so on, is happening, then I guess I question whether we ought to be more aggressive than saying that we think ACOs should move to two-sided risk and really try to imagine what the next phase or the transition would be for the MSSP. I think it's confounded by the alternative payment model issue on the physician side, because there CMS is clearly articulating an interest in really staying with the two-sided type of ACO for purposes of an alternative payment model.

So this feels like training wheels that were designed to eventually go away, but from experience I can

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tell you the longer they exist, the harder they will be to transition to anything else. So I'm just saying that I think we ought to think, as a Commission, as to whether we want to be a little more aggressive about recommending what the phase -- next phase should be for the MSSP model, which are, you know, substantially most of the ACOs.

For the Part D drug issue, really, there are two issues. One is that, I think as Jay pointed out, there may be drug expenditures that actually save on service expenditures, on the ACO side. There's also the issue that ACOs are managing the Part B drug expenditure. You know, that's part of the benchmark, but not D. So the -- you know, the tradeoff between self-administered and physician-administered drugs is not taking place as part of the calculation.

So I think that, like I think Paul and Jack, I hope we can think about ways that that can be brought more in alignment, recognizing that the ACOs will not become Part D plans.

I like Bruce's idea of using -- potentially coming up with metrics for assessing Part D plans' success in kind of coordinating care, because I don't think it's

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always going to be managing costs down. It might be managing costs so that service use goes down. But some metric that captures that interaction between service and drug prescribing, and giving Part D plans credit if they're actually in -- working with ACOs on that particular thing.

The other thing I wondered about, and I think this is probably way out there, is whether there would be any mechanism to have Part D plans make an arrangement with ACOs, particularly two-sided risk ACOs, with a prospective assignment, to take on the Part B management for the ACO, understanding ACO is going to be held accountable. But is there some way that the drug plan can manage B and D drugs, if you will, or self-administered and physician-administered drugs, in such a way that those tradeoffs are made together rather than separately, by the physicians on one side and the drug plan on the other side? So recognizing physicians are also on the other end of the drug plan. It just feels like there ought to be some way for that tradeoff to occur more in --

MR. GLASS: Do you know if that's happening in MAPD plans, with --

MS. BUTO: I don't. I don't know if any of our -

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MR. GLASS: It would kind of make sense. I mean, if that's --

MS. BUTO: They ought to be able to do that.

MR. GLASS: -- you would think they would be doing it.

MS. BUTO: Right?

MR. GLASS: Yeah. I don't know that.

MS. BUTO: I think that's worth looking into, if we might check into that, to see if some of the plans are actually already doing that in some way.

So it's just a matter of using -- maybe there's a reward system or a quality metric that D plans can be given credit for to help with this overall crossover issue. But it's tough, but I think we ought to try to go back to that.

MR. GLASS: And I think, Bruce, you were saying the other way around. Give the generic prescribing --

MR. PYENSON: Yeah, just measure the attributed lives and just for the ACO ignore the Part D plans, was my thought.

DR. MILLER: I think you're saying the same thing. That was the clarification I wanted to tease out

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because I think Paul said a version of this. Somebody over there maybe have said it too, and then Bruce said a version. And then you turned it a different way. I took -- just to make the point, I took Bruce's GDR point -- the generic dispensing rate thing -- metric as saying if you had a low GDR for your ACO population, the ACO would get some credit. Was that what you were saying, Bruce?

MR. PYENSON: Yes.

DR. MILLER: And, Kathy, you flipped it. So, at some point, we'll have to talk through -- I am going to want to talk to you about --

MS. BUTO: Yeah. And, as I said, I don't -- and I don't think we -- this is really off the top of the head, so I'm thinking let's just think more about how we can link these two together in a meaningful way, whether it's that approach or other approaches. I just think it's not impossible, and we ought to figure out something.

DR. MILLER: I completely hear you.

DR. CROSSON: Okay. Hands? Bill, Bill Gradison.

MR. GRADISON: I'm glad we have the ACOs out there. I think a big mistake was made to create so many and to make them -- because I didn't think -- I don't think

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as a demonstration that such large numbers were necessary, and it also makes it, as I think Dave or Kathy -- I'm not trying to put words in your mouth -- may have suggested -- I will definitely say I think that it's going to make it impossible ever to get rid of them. That wouldn't be a bad thing if we had confidence that the measurements were telling us what we really want to know, which is whether they are achieving savings and improving quality at the same time. In many ways, I think it's such a random matter that maybe -- to say there's savings as sort of an artifact of how the baseline is created.

And I think there will be pressure over time by these institutions to change the bench line or maintain a bench line, to their benefit, which is perfectly understandable.

I had hoped long term from a strategic point of view that ACOs, as many have talked about, would be a step in the direction of MA, and at the very least, I would hope over time that you could monitor, to the extent you can find that out, how many ACOs that dropped out of the program do so by moving the other direction; that is, in the direction of becoming MA -- the number may be zero. I

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really don't know, but I think that that would be extremely useful to see and to attract over time.

Bottom line, I think as a policy that there should be something to nudge these institutions in the direction of having to make that choice, and the only way I can think of is ultimately to require a two-sided risk -- and with a meaningful number. I mean not just some nominal 1 percent or something, but enough to make it interesting and force them to make a choice. And I believe that the recommendations that we made should be consistent with that nudge idea.

DR. CROSSON: Bill Hall.

DR. HALL: Interesting discussion and probably an extremely important topic for us in the next year -- or some of you in the following year.

I think there are three models that we have to look at. There is the hospital-based ACO. There's the physician-based ACO. Then, as Bill Gradison just mentioned, there is the MA plans around the country.

In communities that have a very strong MA penetrance in Medicare, like where I come from, 75 percent, there's very little interest in ACOs. Physicians, while

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they may bridle a little bit by the increased administrative burdens, understand that it's a modification of fee-for-service medicine. They feel the sense of control. They can make decisions, and by the -- they assume it's a two-sided model. Just like life, sometimes you win and sometimes you lose.

And I find that in other parts of the country, the hospital-based systems tend to be very regimented. They tend to much more look at health care providers as integers than to a system of care, and that they can be replaced by other providers. And I think it's caused a certain amount of change in the physician culture.

I think maybe Alice maybe mentioned something about this. So what's in it for the provider? It's not only the money, but what is the nature of medical practice? And I think we need to look at that somehow. I'm not quite sure how we do that.

I think we could learn a lot, at least for the moment, of really looking again at the super ACOs, the ones that seem to work really well, particularly the physician-based ones, and see exactly why they are successful. I don't think it's all going to be financial. I think it's

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going to have a lot to do with the nature of the practice of medicine, and I think at some point, we really need to take that into consideration.

Basically, I hope what our goal here is is to enhance the value proposition of quality care to Medicare patients, irrespective of what initials we use for the system. I don't think there's going to be one system that's going to win this battle, nor should there be. I think there's going to be some heterogeneity in practice around the country, but as a start, I would really look at the successful physician-led organizations and see what we can learn from them.

DR. CROSSON: Thank you. Craig.

DR. SAMITT: So thank you again for the excellent report. I must say, though, that I found the results incredibly unsatisfying, to tag onto what others have said.

I think the reason we've all encouraged to others' points, ACOs is really to drive growth of delivery system accountability for quality and cost, not just volume. And my concerns with the results is it feels like we're not making the progress that we would like, most certainly not the progress we tend to see more in the MA

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space.

And I'm concerned that the reasons are there are two attributes that are kind of necessary for us to make sure that ACOs are successful. One is a clear understanding of what the super performers are doing versus the non-super performers, and the second is sort of a clear path forward that really inspires and motivates other organizations to move to the next step, either move into the ACO programs or to move to two-sided risk or to move to capitation.

And so the first part about understanding, just it was remarkable to me, even the results, that Pioneer versus MSSP are not significantly different. Even Pioneer is not achieving savings. It's 1 percent versus the benchmark, and some of the higher-performing MA plans are double digit. So 1 percent is sort of a drop in the bucket versus the waste that we suggest exists in the industry. So it feels, to other points, that it may not be working.

But, also, some of your analysis suggests it's not the benchmarks that are the differentiator. It's not prospective attribution versus retrospective. It's not even two-sided risk versus one-sided risk. So it feels to

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me, to Bill's point, we need to be going deeper to understand what are the real attributes that are determining the winners and the losers.

We've been studying this within the Anthem ACO, and one of the things that we may find is it's not just about the payment model. It's about the capabilities within the practice, whether it's leadership or data availability or technological solutions or care model designs, and so it feels to me that the correlation analysis doesn't quite get at the variables that distinguish the best from the non-best. And I think we have to go deeper. So that's the understanding.

The sustainability piece is even more concerning. If we essentially say that the best correlate is service use, well, once the service use comes to a better baseline, then what will motivate these practices to continue in the ACO program?

So, to my point about a clearer path forward, we need something that either offers more flexibility, more attractiveness, future opportunities for these delivery systems to keep -- move down the continuum, or I just think that we're going to see regression. And then, at the end

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of the day, I think we'll see traditional fee-for-service plus its variations under MACRA or MA because I don't see longevity to the program unless we do something to keep moving things forward.

And then, in terms of Part D, I guess I'd echo Paul and Jack's comments. I'm not willing to give up. I don't remember if we did the analysis of Part D cost in ACOs versus MA, but I think the aspiration or the belief is that there is an important component to controlling drug costs to have clinicians care about generic prescribing and other utilization measures of drug. And so the value of this is tremendous. I think we have to find a way to make it work. Given the various suggestions, I just think we should stick with this and come up with suggestions to link Part D, to some degree, with ACO.

DR. CROSSON: Sue.

MS. THOMPSON: Thank you for this chapter, one that I was very, very interested in and I'm excited to make comment on.

As a recovering Pioneer and now finding herself in the middle of the NextGen world, I am really worried we're going to throw the baby out with the bath water here,

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and even the tone of our conversation, it feels heavy and discouraged.

Alice referenced chemistry that occurs when you take on the work of moving a system who has been orchestrated to succeed in a fee-for-service model to become one team and work together to deliver a care-coordinated product to patients, and oh, by the way, we may be able to demonstrate on the process metrics that we've improved quality and reduced cost.

But in the challenge that we face in terms of improving the Medicare product for our country, the opportunities that reside within this ACO work, I just feel very strongly we can't throw them away. And to state -- and contrary to one of the opinions expressed, I don't think we have enough folks involved in this work, and I think perhaps what we need to be thinking about is how do we create an environment that encourages physicians to want to participate in these models and not be afraid of taking risk.

Most recently, with the MACRA proposed rules, I mean, we, being in an advanced alternative payment model, thought we had a great opportunity to get out, talked to

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physicians about becoming involved. And I must tell you, they'll take the risk and the additional work of MIPS before jumping into this risk business because there's not enough benefit. There's not enough carrot there yet.

So, as an alternative to getting into the minutia, I really encourage us to think at a high level and be encouraged to continue in this work and think about how do we create an appetite for more providers, including physicians, to take the lead, because I couldn't agree with Alice more. We need physicians leading this work, but creating enough motivation and inducement to them to want to take on this work. So whether that is in how we benchmark, whether that is in the kinds of incentives we can offer to the beneficiaries to become part and participants in the journey of their health care, whether it's in relief from some of the regulations that can be given to particularly the early adopters, the organizations that get out there in front and that have stayed in here, not because they're making any big margins -- I mean, for every dollar you save in assured savings program, you've likely taken two dollars off your top-line revenue in the fee-for-service world to get there. So there is a mission

motivation here that has kept many of these providers in the game, and I would suggest that we better understand what is motivating folks to continue to want to do this and can we make it affordable that they can say in the business. So I offer those very passionate thoughts that we need to stay in this game.

And last but not least, I think if we think about the ACOs being in the same -- or the upside-downside risk, ACOs being in the same game as MA, then let's make the playing field level between NextGen ACO and MA. Those would be my comments.

DR. CROSSON: Great. Paul and then --

DR. GINSBURG: I find the discussion of my colleagues very, very thought provoking. On the one hand, I think that we don't want to continue long term with the one-sided risk model. As Kathy mentioned, it's losing money. But I've always thought that one of the factors behind the very low participation in two-sided risk has been lack of confidence in the model. So I'm wondering if, in a sense, we could come up with something that combines our exacerbation with a one-sided risk model -- we don't want to continue it forever -- and use that to actually get

people to grapple with how can we improve the model.

There's certainly been improvements that have been reflected in NextGen. I'm concerned that the improvements are not getting into MSSP, and ultimately, we should probably talk about can this model survive without beneficiary engagements where beneficiaries actually choose an ACO to affiliate with, have incentives to be steered to the ACO, ACO's network of physicians, of specialists and the like, and facilities. You know, maybe this is a time to really bring this up, the need for some significant improvement of the model, because we're afraid of one-sided risk being institutionalized and with a just continued loss to the program.

DR. CROSSON: Pat and then Jon, and then we have to wrap up.

MS. WANG: I agree very much with so many of the things that have been said, and it's a great discussion stimulated by a great paper.

I think the topic brings up different priorities. One that's been discussed is beneficiary choice, and the other that's been discussed is really delivery system reform.

As far as beneficiary choice is concerned, there are really only two choices. There's MA, and there's fee-for-service -- because most beneficiaries don't choose to be in an ACO. They really don't even know that they're in it, and those choices, I think, continue to exist, no matter what. MA plans, if they're good, they will sell themselves. People who want to stay in fee-for-service, I think the goal is to have a delivery system that is more able to implement population help, better practices in a fee-for-service world.

As far as delivery system reform is concerned, to the point that some have made here, I do think that -- personally, I feel that ACOs are quite important, despite the lack of overwhelming excitement with what they've produced so far, because in order to sort of turn the boat or turn the ship, especially for hospital systems, which may show modest savings or success, it's critically important to have programs that encourage that because you're talking about cultures and embedded processers that are very, very difficult to change.

So, to me, within the constraints of budgetary considerations for the Medicare program, this is a very

high priority. I think that delivery systems, providers who become really, really good at it, will go to MA. I mean, that's the natural progression. But for those who are still in a predominantly fee-for-service environment, this is a very worthwhile effort.

I think the discussion on Part D is so incredibly important. I don't have any suggestions about how to link incentives and sort of financial ties and reporting. That sounds kind of complicated. Maybe it's something that people can think about, but at a minimum, I think it's very important to update the evaluation of the per-beneficiary spend or the overall spend with the information from Part D. Whether it's generic substitution rate, total cost of care, or medical costs lower because Part D spend is higher, which may be completely appropriate, I don't think you can evaluate the cost without including the drug spend in there.

There are quality metrics that MA plans are held to that are very, very heavily weighted -- medication adherence, high-risk medication management, things of that nature. From a quality perspective, you could introduce those or consider introducing those into ACO models just to

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see is there a better result for the beneficiary as a result of more attention to prescription drugs. I think that would make the analysis much more robust and our understanding of what is success and what is not success a little bit more nuanced.

As far as the benchmark issue and sort of the concern about the cost to the Medicare program, I do think that there's been a lot of good discussion here that should be the basis of further thinking about maybe it -- it's not such a small thing that we're judging success or failure according to the current baselines or the current benchmarks. I think the benchmarks do -- to the team's discussion here, do need to be more refined because, if you just keeping comparing against yourself, at a certain point, where are you? It's sort of a point of diminishing returns. There should be at least some comparison. What's the MA benchmark in the area? What's the regional fee-for-service spending in the area? How do these numbers compare to those other freestanding, independent benchmarks? I think it would be very important to -- but, again, I think it's important to keep thinking about how to make ACOs successful, because I think they're very important. You

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have to stay within the budget, but they're very important for delivery system reform.

And I think they're equally important -- people are focused on physician-led. That's fine. There's a reason that physicians don't want to take risk for the hospital side. Hospital systems have to have incentives to change their culture, change themselves, or frankly, none of this works. They have to have some skin in the game, and they have to feel that there's some benefit for them to move in that direction.

DR. CROSSON: Thank you. Jon. And then I'm sorry.

DR. CHRISTIANSON: I'll --

DR. CROSSON: I'm sorry. We've run over our time, and we've got barely enough time for the next topic.

I will sum up very quickly. ACOs are important. We all believe that. I believe it.

Disappointed with the progression so far. If you'd have asked me ten years ago or even seven years ago when we put out our first ACO report, would it be this situation right now, I would have been very disappointed.

On the other hand, I think the points that have

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been made here are right on. This should succeed. It will succeed. It's going to take a long time. There have been perhaps some design missteps. We need to continue working on those to the best we can.

I completely agree with that -- the successful models that hopefully will evolve need to create opportunities for shared savings, which are more robust than what exists right now, and that the key to that -- or keys to that are the issue of the hospital fees, because when you think about it, there's only so much potential gain or savings that can come out of physicians' own part of the pie here, even with respect to referral costs and high-cost procedures and all the rest of that.

Most of the opportunity really exists in managing the downstream cost, hospital care being principal among that, post-acute care and pharmaceutical cost, and the models we have right now are inadequate. I mean, if a hospital is working off a fee-for-service, fill-up-the-beds model and the physicians or even an ACO associated with the hospital are trying to work in the other direction, it's not going to work.

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And so to the extent that as a commission, we can come up with ideas -- and this is going to take some time -- you know, even ones that are perhaps a little sharp-edged, as some comments have been, then I think that's appropriate to our role. And I do apologize that we have to end this discussion.

Yes, Mark.

DR. MILLER: You'll get another chance. We will have a set piece where we talk about the risk. So all this conversation will be brought back, and we'll start working up some thinking on Part D as well.

DR. CROSSON: Okay. David, Sydney, Jeff, thank you so much.

[Pause.]

DR. CROSSON: We're going to push right ahead here. We're going to take a look at the issue of measures of hospital use for long-stay nursing home facilities, and, Stephanie, it's your ball.

MS. CAMERON: Good morning. Before we begin, I'd like to thank Carol Carter for her contributions to this work.

Today's presentation focuses on findings related

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to the development of risk-adjusted measures of hospital and skilled nursing facility use for long-stay nursing facility residents as follow-up from our September meeting. As you'll recall, last month we discussed strategies nursing facilities use to reduce avoidable hospital use and some outcomes to date from recent initiatives to reduce hospital use among the long-stay nursing facility population.

As we discussed in September, a majority of long-stay nursing facility residents are Medicare beneficiaries, creating an easily defined population to target for better care coordination and quality of care. This population is primarily comprised of residents who are dually eligible for both Medicare and Medicaid. While the facilities that we are discussing today are typically the same facilities who provide care under Medicare's skilled nursing facility benefit, the measures we developed are focused on the long-stay resident population.

Existing literature has shown that a substantial portion of hospital admissions of long-stay nursing facility residents may be avoidable through better prevention or management by the nursing facility.

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Transferring these residents to a hospital for conditions that could have been prevented exposes beneficiaries to several health risks and unnecessarily increases Medicare program spending.

Last month we discussed a broad spectrum of topics related to hospital use of long-stay nursing facility residents. Today I will focus on the measures we developed to capture the rates of hospital use and use of the SNF benefit for this population. Specifically, I will present the rates of potentially avoidable hospital admissions, all-cause emergency department visits and observation use, and skilled nursing facility use. I will also discuss spending implications associated with hospital and SNF use of this population. Please note that my discussion on Slides 7 and 11 will include refinements since you received the mailing materials. We seek input regarding your interest in incorporating a measure of avoidable events, such as potentially avoidable hospital admissions, into a SNF quality reporting or pay-for-performance program.

First, a brief description of the measures used for this analysis. For reference, a detailed discussion of

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these measures was included in the October mailing materials.

We created a measure of potentially avoidable hospital admissions based on 20 categories of conditions we reasonably expect to be managed or prevented in a nursing facility with high-quality care. I want to note that the goal of this measure is not for nursing facilities to become acute-care hospitals. Instead, facilities with high rates of potentially avoidable hospital admissions could adopt practices currently being conducted at facilities with lower rates, including the increased use of physicians and other health professionals and access to ancillary services including on-site laboratory services and X-rays which are available in about 80 percent of facilities.

It is important to keep in mind that included conditions are considered "potentially avoidable," not necessarily "always avoidable." Therefore, we do not expect the rate of potentially avoidable hospital admissions to be zero, even at facilities that provide the highest quality of care.

Another dimension of hospital use is the frequency of ED visits and observation stays. We created a

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combined measure of emergency department visits and observation use to capture instances where a beneficiary was transferred to a hospital for diagnosis or treatment but not admitted as an inpatient. Some researchers contend that services provided to long-stay nursing facility residents in the emergency department could have been prevented through timely access to on-site ancillary services, and for this reason we included all ED visits and observation stays in this measure for purposes of our discussion today. We recognize, however, that the Commission prefers measures where the provider has some level of control and again stress that we do not expect the rates of ED and observation use to be zero, even at the top performing facilities.

Next we looked at two measures of SNF use to detect whether some facilities are attempting to maximize Medicare revenues. Facilities can increase Medicare revenues from SNF use in two ways: increasing the number of SNF days per stay and increasing the frequency of SNF admissions. Facilities with a high number of SNF days indicates that the long-term residents either used the SNF benefit longer than average or more often than average.

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Jack, last month you asked about a measure of SNF use triggered by a hospital admission. For this, we developed a second measure that focuses on the average number of days between when a beneficiary was eligible to trigger a new benefit period and the hospital stay that triggers SNF use, or a measure of "gap" days. Facilities with a high rate of gap days indicates more frequent use of the SNF benefit. Our regression model for this measure was unable to explain the variation across facilities, with a calculated r-squared close to zero; therefore, we are not providing any detailed analysis for this measure.

We risk-adjusted each facility's rate based on its mix of resident characteristics including conditions, function, and comorbid diseases. Consistent with our past approaches, we did not include socioeconomic status out of concern that adjusting for SES might mask the quality of care provided to poor patients. The Commission is, however, concerned about the fairness to providers. Thus, for purposes of payment policy, the Commission has previously stratified providers by SES to make comparisons fair across providers.

We found that beneficiaries identified as long-

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stay residents in nursing facilities had just over 200,000 potentially avoidable hospital admissions in 2014. This represents about 46 percent of all hospital admissions for this population. We found that long-stay nursing facility beneficiaries had about 500,000 ED visits or observation stays per year and used about 20 million days of SNF care annually. These 20 million days of SNF care represents about 400,000 stays.

On average, the risk-adjusted rate of potentially avoidable hospital admissions of long-stay nursing facility residents equaled 0.8 per 1,000 long-stay beneficiary days. We found wide variation across facilities. For example, the lowest performing facilities -- those with the highest rates of potentially avoidable hospital admissions -- had rates three times higher than the best performing facilities. To provide a sense of what a potentially avoidable hospital admission rate means, the average 100-bed facility with a rate 0.8 would have about 20 potentially avoidable hospital admissions per year. A facility at or above the 90th percentile would have over 30 potentially avoidable hospital admissions per year.

We also found wide variation across the measures

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of ED visits and observation use and SNF days. For example, the rates of ED visits and observation stays for the worst performing facilities were almost four times the rates of the best performing facilities. This variation was even more extreme across the measure of SNF days where the rates of the worst performing facilities were ten times higher than the rates of the best performing facilities.

Using an r-squared, we tested our models to determine how well they explained variation in rates across each of the measures. We found that the percent of variation in rates explained by our risk-adjustment model for potentially avoidable hospital admission was about 30 percent. The calculated r-squareds for the other measures were less than 20 percent.

Given the volume of cases, strength of the model, and similarities of characteristics across the measures, the rest of this presentation will focus on the measure of potentially avoidable hospital admissions.

We found minimal differences in the rates of potentially avoidable hospital admissions across our usual categories of stratification. Instead, we compared characteristics of facilities in the best and worst

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performing deciles. We found that a disproportionate share of urban facilities had rates in the best performing decile, while a disproportionate share of rural facilities had rates in the worst performing decile. We also found that facilities with 100 or fewer beds were more likely to have potentially avoidable hospital admission rates in the worst performing decile.

We did find that several facility characteristics affected the potentially avoidable hospital admission rate, even if the effects were small. Facilities with the highest portion of hospice days or access to on-site X-ray services had lower rates of potentially avoidable hospital use, while facilities with the highest use of licensed practical nurses and the lowest frequency of visits from physicians or other health professionals had higher rates of hospital use.

Given the lack of variation in the facility-level rates across our typical categories of stratification, we considered stratifying the rates based on state as a proxy for numerous state-level policies that could be contributing to the rates of potentially avoidable hospital admission. We found two-fold differences across the

average rates of potentially avoidable hospital admissions and three-fold differences across the rates of ED visits and observation stays and SNF use. Many factors may contribute to this state-level variation including staff requirements, culture regarding end-of-life care, and other state-level policies. These state-level characteristics may work in opposite directions, and since we did not test each of these variables independently in the models, we do not know the degree that each one contributes to the state's average rates.

We found just over 200,000 potentially avoidable hospital admissions per year for this population, and we roughly estimate that these hospital admissions cost about $1.4 billion in 2014. This estimate excludes any additional spending on SNF care following a hospitalization or clinician billing during the hospital admission. Using aggregate data, we estimate that physicians and other health professionals bill about $200 million annually to care for long-stay nursing facility beneficiaries during a potentially avoidable hospital stay.

Brian, last month you ask about the financial incentives nursing facilities have to transfer

beneficiaries to a hospital for treatment. If we consider the post-acute care SNF stays for this population, it would not be unreasonable to expect between $2 and $3 billion in SNF spending associated with potentially avoidable hospital admissions each year, given that the average Medicare payment per SNF stay exceeds $18,500. This $2 to $3 billion represents between 7 and 10 percent of all SNF spending.

We estimate just under 500,000 combined ED visits and observation stays in 2014 which totaled about $300 million in spending. This means that spending on hospital use for potentially avoidable hospital admissions, ED visits, and observation stays totaled about $1.7 billion for long-stay nursing facilities in 2014.

We are interested in the Commission's feedback regarding the measures we presented today and input regarding future use of these measures. Improving the quality of care provided to Medicare beneficiaries residing in nursing facilities aligns with the Commission's desire to move toward population-based outcomes measures. To the extent that potentially avoidable hospital admissions occur, the Medicare program is responsible for that

spending. Because we are focused on the Medicare population and most nursing facilities provide care to both short-term post-acute-care beneficiaries using the SNF benefit and long-stay nursing facility residents, we could consider incorporating the measures we developed for the long-stay nursing facility residents into two existing vehicles used by the Medicare program.

First, facilities are required to report on measures for the SNF quality reporting program. These measures are published on the Nursing Home Compare website, and more than half are targeted to the long-stay resident population.

Second, Congress enacted a SNF value-based purchasing program as part of the Protecting Access to Medicare Act of 2014. Congress designed the SNF VBP program to use a measure of SNF readmissions. Facilities will begin publicly reporting an all-cause, all-condition measure beginning in October of 2017, and the payment adjustments as part of the VBP program will begin in October of 2018. Adding other measures to the SNF VBP program would require congressional action.

We seek input regarding your interest in

incorporating a measure or measures we developed, such as the potentially avoidable hospital admissions, into the current SNF quality reporting program, value-based purchasing program, or other suggestions you would like us to pursue moving forward. And with that I turn it back to Jay.

DR. CROSSON: Thank you, Stephanie. Very clear. Thank you to Brian for your question last month. I guess $2 to $3 billion seems like real money. So I guess there's something here. Let's start with clarifying questions.

MR. GRADISON: It sounds that some of the problem here may -- I stress the word "may" -- be a result of some of the SNFs not having a sufficient -- or making sufficient use of somewhat more highly trained staff than they are doing right now, for example, the number of hours from MDs and the level of training of the nurses. Have you made any estimate of the increased cost to the SNFs if that is a factor that could help to improve performance, the increased cost to the SNFs of improving their performance, and what impact that might have on the costs over time on the cost reimbursement to SNFs under the present payment system?

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MS. CAMERON: We have not looked at the impact of additional nursing staff on the nursing facilities' bottom line or in terms of how they would pay for that. When physicians or other health professionals, including nurse practitioners, visit a patient in a nursing facility, they bill for that separately. That doesn't fall under the SNF consolidated billing.

We also did not include an estimate of any added cost for additional physician visits or visits from other health professionals from the Medicare program's perspective.

DR. MILLER: The only thing I would just interject in this, you pitched all of your comments from a SNF point of view, and I know the facilities, both the SNF and a nursing facility -- but then, you know, you could be talking about the SNF population and the SNF bottom line as it's paid for through Medicare, or you could be talking about the nursing facility bottom line, which would then kind of start to move you into the Medicaid world. So I just wanted to make sure that you had that distinction in your mind.

MR. GRADISON: Well, I mean, I'm sure the

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discussion from others will get into this, but I'm trying to understand why is there this 2:1 or 3:1 ratio, and possibly it has to do with the training and skill set of the people doing the work or the frequency -- or, you know, the staff ratios or something of that kind. And so all I was really trying to say is it may be that there are extra costs that would have to be incurred within the system in order to reduce the hospital readmission rate to an acceptable level. I'm just kind of curious what that tradeoff might be.

DR. CHRISTIANSON: So for clarifying questions, we'll come around this way.

DR. HALL: This is going to be a valuable contribution. I'm worried about the term "potentially avoidable." That opens up a huge snake pit here. In the -- am I pronouncing it right, Providigm? What is the company you used to --

MS. CAMERON: Providigm.

DR. HALL: Providigm. Is there a little more granularity available in terms of what these potentially avoidable admissions are, just categorization by type of disease or something? I think we really need to see that

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in order to know whether we've got the right mousetrap here to catch the rats in the system.

MS. CAMERON: Absolutely. So in the appendix to the mailing materials, I did provide the broad -- the categories of conditions that were included in potentially avoidable. If you're interested, I do also have the ICD-9 codes, if you're interested in providing that.

DR. HALL: That's what I'm thinking about, yeah.

MS. CAMERON: Absolutely.

MS. THOMPSON: Stephanie, thank you. Do you know or can we determine what's the variation state by state in terms of staffing requirements for nursing facilities and SNFs? Because I'm just wondering what's the variability in terms of LPN versus an RN 24 hours, et cetera.

MS. CAMERON: So I don't have any state-level minimum staffing requirements. You know, as you're well aware, there are 50 states plus D.C., and they all have different state-level policies. And even for a state-level policy one might consider as simple and straightforward, for example, the bed hold policy, it's really not because they're very nuanced in terms of who it applies to, for how long, what's the payment rate for those days. So it's

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quite a bit of work doing this state-level piece.

That said, you know, I think depending on what direction we take today, we could consider that for the future. But for this presentation, I don't have that information.

DR. GINSBURG: I'm not sure if this is a clarifying question or a very substantive question, so let me just raise it, and you can just do the clarification first.

You know, what struck me is that this is about long-stay facility patients and the costs they impose on the Medicare program when they're hospitalized or go to the ED more than they should. But Medicare doesn't have any tools to really get at the long-stay facilities because it's not paying them. In a sense, it only gets in if the patient happens to be in a SNF and the SNF is perhaps in the same organization as a long-stay; maybe something could be done. But, you know, I wonder if this is something where we should really be thinking about how to engage the Medicaid programs into their doing value-based purchasing for long-stay facilities where the costs imposed on Medicare are particularly large criteria.

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MS. WANG: You touched on this, Stephanie. Is there a way to see, in the states that had the higher ratios of inpatient admissions and then, you know, retriggering the SNF benefit to bed hold policies of any type? I understand that there are a lot of nuances underneath it, but just as a first cut. Because just, for example, Paul, in response to the question that you raised -- because this is really the confusing part, right, because Medicaid programs have different requirements, and they have different payment rates, and, you know, all of the rest, but in terms of the tools that Medicare has, those are two of them.

But, you know, another one -- I'm just making this up on the spot -- is that if there was -- if we did feel that there was a pernicious interaction in states that somehow the Medicaid bed hold policy was creating a higher rate of, you know, potentially avoidable admissions that retriggered the SNF benefit, maybe Medicare should pay less for the SNF stay in those states that had those policies. I mean, it's a very indirect way of getting there. But to you point, that that's what Medicare has control over. It doesn't have control over what Medicaid pays.

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MS. CAMERON: So there's quite a bit of literature about bed hold policies and whether it's readmissions for the SNF population or admissions for the long stay population. David Grabowski has done quite a bit of research in this area, and has found statistically significant effects of state bed hold policies relative to the rates that I mentioned.

I did a very brief analysis -- and again, it was a very top-level of classifying states into yes or no bed hold policies, and I caution that for reasons I just mentioned, and I think you would probably agree with New York, maybe on paper there is a policy. But there was a policy that has been fading out, and I think at the time of this data it might have still been in play. But they are -- they vary very much.

But I did briefly look, and I did note that if you look at kind of the states with the highest level of hospital admissions, more of them had a bed hold policy than the states in the lower levels. So we did see what has been shown in the literature, and again, I caution it was not a -- you know, we did not build it into the model, but at first glance there was a trend there.

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DR. CROSSON: Clarifying questions going around. Brian?

DR. DeBUSK: First of all, thank you for the presentation.

Could you speak specifically to -- and I know Bill touched on this, but for some reason I can't resist a snake -- could you speak specifically to the incremental value of using the avoidable inpatient, or the admission, versus using an all-cause admission indicator? What's the incremental value, number one, in this situation, and then what are the tradeoffs between using a more broad process measure versus something more specific to nursing and facilities?

MS. CAMERON: Sure. So we built this model based on underlying conditions. We defined potentially avoidable based on a series of underlying conditions, and I think, you know, one could agree that there are likely going to be admissions in that potentially avoidable category that are not, in fact, potentially avoidable, and there are likely going to be potentially avoidable admissions that we didn't capture by this measure. I think, historically, the Commission has preferred measures that tend to be more in

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the provider's control, and we have tended toward potentially avoidable for that reason.

In this instance, when we looked at the all-cause measures, when I compared the facilities with rates at the 10th percentile compared to those at the 90th, there was about a two-fold difference -- that's all-cause two-fold difference. But when we looked at the potentially avoidable, there was a three-fold difference. And to me that suggests that there is -- because there is more variation, there can be likely more control over those admissions.

The Commission has also done other work in the hospital realm, looking at hospitals readmissions, and found that following the implementation of the hospital readmission program the rates of those considered potentially avoidable did go down faster than kind of all-cause.

DR. GINSBURG: Can I follow up on that?

DR. CROSSON: Yeah. I was going to do it too. So, admittedly, Brian, there's also a -- in addition to, you know, potential financial differences, an topics piece here, which is, you know, it's more understandable to

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people who are put in the position of having to manage this, that they're being expected to manage things that are potentially avoidable, and the expectation is to manage things that are not potentially avoidable.

DR. DeBUSK: Well, my thinking was just around, as we try to use broader measures, you know, for example, opposing condition-specific measures, I was wondering what the incremental value -- and what I'm hearing Stephanie say is that there is increased specificity in going with that all -- with the condition-specific measurement of inpatient admission versus an all-cause.

I'm just trying to think of this in the larger picture of, you know, if every time we look up an inpatient admission I need a definition behind it of what specifically causes that admission or readmission, I'm just trying to wrestle with the tradeoff between having something that's broad and generic and easily used. To your point earlier, this is a -- I wouldn't say imperfect, but there will be condition-specific things here that will still result in an admission. This is a -- this is never a theoretically zero value.

So knowing that we can never drive this value

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truly to zero, I would sort of call it an imperfect measurement, and I don't mean that in a pejorative sense. It's just imperfect in that there will be admissions, even when quality care is provided. Knowing that it's an imperfect measurement to begin with, it makes you wonder if we're better served falling back on a more generic measurement that everyone understands, that could be easily traced.

DR. CROSSON: Okay. Paul on this point.

DR. GINSBURG: Yeah, pretty much what you said, Jay. I was just going to use the term "political feasibility." I think it's much more feasible, you know, to use a potentially avoidable because of the -- you know, just the lower use of penalizing people for things they shouldn't be penalized for, even though I agree with you that we would accomplish more if we were focused on all-cause.

DR. MILLER: And if I could just follow-up. Sorry, I don't want any of it on the record, so --

[Laughter.]

DR. MILLER: -- whenever I'm thinking out loud.

I do -- I just want to comment on, you know, the

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-- I would call it the fairness issue, and at risk of opening David up on his favorite topic, you know, it is part of this whole package of when you're looking and trying to measure quality, trying to take a fairness posture relative to the provider. And, you know, you could think of the conversations we've had elsewhere on, you know, SES, but this is also on the whole continuum of when you're asking people to respond, trying to do it in a fair way, and in my mind I classify it in that same vector of my brain, where's like, well, we're doing it for that -- in part, for that reason, which is not inconsistent at all with what the two of you were saying.

The second thing I would get you to focus on is you were imperfect and, you know, harder to understand, perhaps. I want to kind of draw you back up and remember how this would end up being used and executed. And I just wanted to drive -- Stephanie said this but I want to drive this home. None of this would be a case by -- well, I'm sorry. One other sentence before I say that. You know, if you go to an all-cause one, it will also never be driven to zero.

You know, so, you know, that -- I don't see that

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as a distinguishing characteristic. It's more a question of -- or the point I wanted to make is, it's never a case-by-case calculation. We're not asking people to think of this case-by-case. Any measure you use, all-cause or potentially preventable, will be a rate, and then whatever that distribution is, whether it's all-cause or potentially preventable, you'll look at the distribution and say, "Here's the threshold, and above that you're okay, and below that you're not." So, in a sense, any imprecision or difference in the measure, you can deal with in the fact that you're dealing with it as a rate and thinking about where, on the distribution of that measure you're going to set the threshold and say that's the performance standard.

So I think, in my mind -- and I'm not telling you how to think -- a lot of this kind of back-and-forth on the potentially preventable, all-cause, starts to fall away, and then it reduces to really the comments of do providers see it as fairer that they've been asked to focus on things that some clinician or somebody said "I think you could have had the opportunity to prevent these kinds of things."

Sorry about that.

DR. CROSSON: Kathy, did you have a point on

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this, or are you just getting in the queue?
MS. BUTO: Getting in the queue.
DR. CROSSON: Okay. Alice.
DR. COOMBS: So I had a question after looking at -- thank you very much, Stephanie. Excellent work. Looking at the appendix and the conditions, I remember doing some work at the Board of Registration, where we looked at hospital fall rate, and I noticed that in your Appendix A, is the fractures and musculoskeletals, does that represent fall rate, that they fell out of bed?
MS. CAMERON: It should encompass that.
DR. COOMBS: So there's some falls that -- and I think maybe it might be better to have just fall rate, because if an institution needs to transfer them back to work up -- if they don't have x-rays, like you mentioned in the paper -- they wanted to do a CT scan for someone who is on Coumadin who needs to be ruled out for subdural hematoma. So that would be, okay, I cannot allow this patient to sit here if there's an off chance they've got dementia and a couple of other mitigating, comorbid conditions, where you couldn't decipher, neurologically, what was going on with them. You might transfer them, get

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a CT scan, and they go back to their bed.
So falls is a category where I could see where that could result in a lot of admissions to acute care facilities. So I wonder if falls, by itself, deserves a line by itself, because of the increased propensity. And I know, even in acute care hospitals, falls are huge. I mean, there's some institutions where it's like 4 or 5 percent. So, I mean, it may be something that falls out.
And that's a safety issue, because in our hospital we have bed monitors, you know, if someone gets close to falling out. There's also a workforce issue, in terms of the number of FTEs you have working, the nurse -- licensed nurse practitioners who are on the shift, you know, the ratios are down.
So thank you so much for this.
MS. CAMERON: So just a clarifying question to your question. There currently is a fall measure that's separate and reported on nursing home compare for the long-stay population. When you say break out, are you interested in seeing kind of the associated codes with that, or looking at a rate? I -- just, what are you generally looking at?

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DR. COOMBS: So when they combine -- say, for instance, you had a conglomeration of all of these things, and that if you put falls in as a cause for readmission, would that push you over the -- would that push you over the margin? I mean, they're going back to the hospital, and I don't know how -- how does it fall out if you have a fall and that's the diagnosis for which you are going back to the hospital? Would that fall out under this category, under this appendix?
MS. CAMERON: That should be captured by that -- by the conditions in that line, and all of that would be added into the facilities rate. Because, again, we're not looking at each hospital admission on a case-by-case basis. So, I think all of that should be kind of incorporated into a facilities rate. And then to the extent that you would either include or exclude, I think this goes back to what Mark was explaining, where, you know, if falls were excluded from this rate then the rate -- the distribution would all come -- or the rates in each part of the distribution would come down and it would depend where you set --
DR. COOMBS: It depends on --

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MS. CAMERON: -- the threshold.
DR. COOMBS: That would depend on the institution, because some institutions may have more falls, based on their --
MS. CAMERON: That's right.
DR. COOMBS: So my question is, should that be -- for fairness, to be included in that? So, say, for instance, if you take out falls as a cause for hospital admission, there are some institutions that would -- are going to fare a lot better than others.

MS. CAMERON: That -- that may be true. Yeah, that may be true.
DR. CROSSON: Questions? Amy.
MS. BRICKER: So back to Bill's point, around the physicians and the impact that a physicians has on a facility. Is it possible to determine which have access to telemedicine, and while not widespread -- I don't even know what percent do -- if they would look more like those do or do not have a physician presence? I realize in the rural setting maybe it's just there aren't enough physicians, and if those facilities had access to a physician virtually,

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would they see and fare like those that had a physical physician present?

MS. CAMERON: So the only data I know is from the CMMI demo that we discussed last month, and that -- one of those sites did use, and is still using, telemedicine. It did not seem to have a high level of take-up, and it seems to be a fairly new technology, especially in these facilities. There have been some studies that have recently come out discussing this point, and the results seemed promising. I am not remembering offhand how many facilities they looked at, but I'm happy to get back with you with that information. I think it is something we can consider, moving forward.

MS. BRICKER: Thank you.

DR. CROSSON: Kathy.

MS. BUTO: I'm just trying -- Stephanie, one of the things I was really surprised to see was this section on dual eligibles, where -- and I don't know if you were surprised, but I was surprised to see that dual-eligible status does not appear to be associated with either higher avoidable hospitalizations or ED visits, and was actually associated with a lower use of SNF days. I think the -- I

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mean, I can remember some time ago testifying for the Agency, and one of the big questions was aren't facilities using Medicare, essentially, to offload Medicaid costs by getting patients -- having patients admitted to the hospital, going into a Medicare stay and then going to SNF days? And what we're finding is that doesn't appear to be true, based on what this section shows.

MS. CAMERON: Well, what we found, in terms of the dual eligibles was that other things in the model appear to be capturing the characteristics of the dual-beneficiary population, whether it's relative frailty, certain comorbidities, age, for example. So we did include those, and then when we looked at it with dual eligible, it didn't make a difference one way or the other.

One thing I do want to caution about, in the kind of last column of that table of SNF use, is we don't know -- because of the way that was measured, we don't know if that means that facilities with a high kind of number of dual eligibles have fewer SNF stays or lower -- shorter SNF stays for that population.

MS. BUTO: Okay.

MS. CAMERON: So that part isn't clear, and we

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tried to get at, I think, what you're getting at, through that measure of gap days, which ended up not --

MS. BUTO: Not showing anything. Right.

MS. CAMERON: Right.

MS. BUTO: Yeah. I just think that's, you know, at least the urban myth goes in the other direction, which is that NFs, nursing facilities, or SNFs -- NFs really have an incentive to -- for duals to have the least -- whatever reason there is for a hospitalization to occur, have them admitted to the hospital so they go into Medicare stay. And that, from at least this analysis, does not seem to be a strong indication.

DR. MILLER: I would just say this -- what you two just said to each other, if I had to say one sentence, it doesn't disprove what you're saying. She's just saying that the fact -- when you go through a multivariate model, the factors that may be associated with the dual model are picking up the variation and the dual --

MS. BUTO: Right. Right. But what I was saying, implying more of an intent on the part of nursing facilities, and this is the implication in many of these hearings that you attend, that there is a nefarious

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motivation to get Medicaid -- Medicare to pick up the cost and to take -- reduce the cost in the nursing facility of those dual eligibles, at every opportunity where there's a possible hospitalization.

I don't see that here. The frailty and other factors would be legitimate reasons, potentially -- or not, depending on what we think about the avoidable conditions -- for admitting those patients to the hospital or ED.

But I thought Stephanie was addressing the SNF days, whether it's a matter of a short stay or more days, or whatever.

DR. MILLER: The other thing I would say -- and this is always really dangerous because I feel like I have some sense of what's gone on here but not as much as I probably should to ask this question.

But your nursing facility population here is also -- it's like people who have 100 days?

MS. CAMERON: That's right. So the population we started with was you had to have at least 100 days in the facility, and then starting at Day 101, that's when our measures began counting, if you will, or that's when -- how the measures were developed, after that 100th day. And you

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will find there was a very high percentage of dual eligibles in that population.

DR. MILLER: And if I could right there, I wanted -- the other thing I want -- I still don't think this myth has been -- I don't think it's a myth. Let me just put it that way.

And I think some of the conversations you and I have had, Pat, I think, I think it is a true phenomenon. Whether every state and every patient and all the rest of it, I'm not saying that, but I do think it goes on.

And I think another thing to keep in mind here, there's a certain segmentation of the population because we're focusing on long-stay nursing facilities. So you're not looking at the whole distribution, and so I think that could also be playing into some of the results that you're seeing here. To the extent that it makes it very heavily dual, you're not getting variation in dual-ness to go, "Aha! Look, the dual is making a difference."

MS. BUTO: Yeah. But duals are most of this population is what you're saying.

DR. MILLER: Yes. We're not very --

MS. BUTO: I gotcha.

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DR. MILLER: But you're with me, right?

MS. BUTO: Yeah, yeah.

DR. CROSSON: Pat, on this?

MS. WANG: Yeah. That was really my question. Seventy-eight percent of the long-stay residents are dual. So I don't really know how meaningful it is that, when compared to the 22 percent who were not, that there was no discernible difference. They're driving the result.

DR. CROSSON: Okay. We're going to get into the general discussion. Again, we have, unfortunately, run close on time here, so I am going to ask Bill Hall to start off. And then I would ask you, in terms of comments, to be as succinct as possible and to focus them on the questions on Slide 12: yes, no, and why. Bill.

DR. HALL: Yes, no, and why, huh?

DR. CROSSON: I know that's a hard construct.

DR. HALL: That's a hard concept for me.

Okay. This is a very complex population. The average stay in long-term care facilities, I believe, is something like in excess of 2 years, but it's not 10 years or 20 years.

The most probable outcome of staying in a nursing

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home is death, over 90 percent.

So things change a little bit when you look at this population, and the fact that we have a high penetrance of either dualism or people who are eligible for Medicare creates a number of perverse incentives that we need to look at, I think.

First, if you are running a nursing home and somebody gets really sick and you want to provide the best, excellent care for them, no matter what you do, it's going to cost some money this is not in the system right now. You can enhance the staffing levels. You can get more physicians in. But it's probably expeditious, if that money isn't there, to send them to a higher level of care, which is almost always an emergency room plus or minus a hospitalization.

Many hospitals are incentivized, if they can get a Medicare admission in the hospital, if they have available beds, treat them, and send them back to the nursing home. So that the path of least resistance here is inevitably going to focus on the nursing home and the receiving acute care system to accept these patients.

So whatever we come up with, I think it's not so

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much that there's a lot of perversity in the system or people are gaming the system as it is that the incentives are quite logical of why people are doing what they're doing. So I think we need to focus some of our attention on that aspect.

That's why I thought, getting a little more granularity in terms of what this population looks like, it would give us some additional insight into this.

DR. CROSSON: Thank you, Bill. Can I see hands for comments?

[Show of hands.]

DR. CROSSON: Okay. So not that many. So let's start with Pat. Pat, Sue, and Bruce. Okay, Pat.

MS. WANG: So I think this is a very important paper because what we're talking about is quality and beneficiary experience of care. Going to the hospital, even if it's an ED or not, it's like not a good thing, and you pointed that out.

My concern is that whether or not facilities are staffed to prevent potentially avoidable hospitalizations is very dependent on state licensure laws, staffing requirements. What does Medicaid pay as the per diem for a

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long-stay resident, because they're the one who's picking up the bill, to support what we would like to see as quality?

So I'm hesitant about incorporating the measure into VBP because I feel like it's a little unfair based on the state of the nursing homes. I may be mistaken, but I don't think that there are sort of national staffing requirements that you can have a common expectation about things being avoidable.

That said, I think that including it into nursing home compare as sort of a consumer transparency tool is fair because somebody should know that if they're putting their mother into a particular facility, then her chances of getting admitted to the hospital are higher, maybe through no fault of the facility, but they may want to know that if it's potentially avoidable. They may want to know that. So I think that that transparency has value.

The third thing -- so, yes, this is part of the yes now -- have we ever -- I mean, I am -- so there's quality, and then there's the sort of maybe pernicious incentives that affect overutilization of hospital settings in order, perhaps, somehow in somebody's consciousness to

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trigger a higher rate of SNF payment, and States have incentives here, too, because they shift costs to Medicare when Medicare picks up the SNF tag. Whether the Commission has ever considered modifying payment for a SNF stay according to State policies on Medicaid bed-holds -- I mean, I made it up before in response to Paul's question, but I'm actually wondering whether that might be something.

DR. MILLER: If I followed the second point that you were making -- and if I didn't, redirect -- we did make a recommendation for a readmission penalty for skilled nursing facilities, and in a sense, if a State has a policy that's encouraging that, then those facilities would be likely to be hit more. I mean, all else equal. So, in a sense, it's sort of saying -- and, again, I'm making this up as I go, but, in a sense, if the state has policies that encourage frequent readmission and churning on the SNF side, then that SNF is going to take a hit for that, roughly.

But the thing I would be careful about is, in all instances, when you think about Medicare policy, whether you scale it specifically to State policy, that I would always want you to slow down and think very carefully

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through it because you could be really creating winners and losers in ways that you would want to think through or create incentives for States to change, which you may want. But the externalities, I think you would want to think through the second and third order.

DR. CROSSON: Sue.

MS. THOMPSON: I'll be quick. Again, thank you.

I'm quite supportive of incorporating these measures into quality program monitorings, and beyond, I would love to have you work with your three peers, who just presented on ACOs, because I think there are many wonderful long-term care facilities out there that are quite interested and intrigued in becoming part of the continuum of care.

I think we referenced in the last discussion where the greater opportunity is to get the bucks out of what's going on within the hospital costs. I would suggest there's a great opportunity in this environment as well, and I think to continue to think about how do we put these pieces together would bring some value.

Additionally, I'd be real curious if there's any information available to us yet for long-term care

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facilities that have engaged in outpatient palliative medicine programs because, if we've taken the time to have conversation with many of these residents about their desires and their wishes and their thoughts about their journey, there would be a lot of these readmissions that we would be avoiding. So I'm wondering if we have enough information out there now about the palliative. I don't know. I just think it would be something to start taking a hard look at because there's some great work going on there.

DR. CROSSON: Bruce.

MR. PYENSON: Thank you very much, Stephanie.

I vote yes on the measures and the suggestions.

I would like to request, if it's feasible, that we correlate the -- see if there is a correlation between the potentially avoidable hospitalizations and the margins that show up in a Medicare cost report. I suspect there won't be any correlation, which might suggest that it would not be a hardship to reduce potentially avoidable hospitalizations.

DR. CROSSON: Thank you. Amy.

DR. BAICKER: Just a brief comment about

something that Pat said around how State requirements would influence staffing, and I certainly agree with that point. But it would be valuable to have the information to compare with in a state how those facilities are performing, which have the same requirements from a staffing level. So I am in favor of those measures being provided as part of the external value-based purchasing program.

DR. CROSSON: So, Amy, the range of variation intra-State, is that what you're saying?

DR. BAICKER: Right. So, yes, there is a difference between the State and another State based on -- you know, they require X number of staff, and I'm not suggesting that you would penalize someone that didn't have the same requirement, given outcomes, but it would be, I think, interesting to know within a State, given they have the same State requirements, how then those facilities perform.

DR. CROSSON: Thank you.

Other comments?

[No response.]

DR. CROSSON: Okay. Good discussion. I don't want to put words in anybody's mouth, but I hear a fair

degree of support here for this direction. And so we will continue moving this way.

Now we have time for the public comment period. If there are individuals who wish to comment, could you please come to the microphone, so we can see. Okay.

So, again, a little bit about the ground rules here for public comment. Please give us your name and your affiliation, if any. We'd ask you to keep your comments to two minutes. When this light goes back on, the two minutes are up. And just note that there are other ways to provide input to MedPAC and its staff through the website, through direct connections to Mark and his staff, and those opportunities can occur before the discussion. But please proceed.

MR. LIND: Thanks. Keith Lind, AARP.

I just wanted to drive home the distinction between preventable -- potentially preventable admissions and all-cause admissions. If you use all-cause admissions as a measure, it creates incentives to delay or avoid necessary admissions and potentially increase unnecessary complications and death.

Thanks.

DR. CROSSON: Thank you.

MR. MULLER: James Muller from the American Health Care Association.

We have a measure currently partway through and have endorsement, recommended for endorsement of an all-cause measure of long-stay hospitalizations for nursing home residents based on the MDS.

One thing that you said, for quality assurance performance improvement work, the work that goes behind it, the nursing home compare measures, the MDS-based ones, end up in the CMS QIES system that gives patient-by-patient enumeration of who is driving the numerators for them to root-cause down the rates. And so I would say the need for sort of just keeping it aggregate, there is a real tradeoff between going with something like the MDS, where you can do that, and not doing so.

And the last thing, I would just sort of support the idea of using discharge MDS assessments for this. They are quite reliable, it turns out. Thank you.

DR. CROSSON: Thank you.

MS. BRENNAN: Good afternoon. I'm Allison Brennan with the National Association of ACOs, and I

thought it was an absolutely wonderful discussion about the ACO program, very spirited.

Just a couple of comments that I wanted to make, I think we're all struggling with trying to understand whether or not the ACO program is or is not a success, and at this point, I feel like it's the analogy where everybody is holding a different piece of an elephant. And they're just describing what's in front of them or what they can see. So it does encourage us all and everybody here to give it a little bit of time so that we can step back and sort of see that full picture rather than just kind of grabbing onto one statistic or one number and thinking that's the full picture.

I think we are starting to see some early analysis in the industry. Michael McWilliams recently put out some research about the 2014 performance, and the thing that was really interesting about that is that rather than comparing ACOs to their benchmark, he was looking at comparing ACOs over time and also looking at comparing ACOs to fee-for-service beneficiaries in their area. I think that's the real key, that we need to dig into that more, but again, we just need a little bit of time.

Focusing just on those benchmarks as a determinant of success, I think is going to be a real downfall in some of the analysis, especially because we're still figuring out the best way to set those benchmarks, and that recently is evidenced by CMS's modifications to the regional benchmarking. Those go into effect as early as 2017, but actually early adopters in the program won't see the regional benchmarking until 2019. So, if they started in 2012, they have to stay in the program until 2019, at which point they would see their benchmark comprised of either 25 or 35 percent of regional expenditures. So that's a big concern for ACOs who have been in the program longer, feeling like they're kind of being penalized by not being able to move to that regional benchmark.

I'm going to be real quick, that we doubly are interested in the conversation about developing new risk models with a more realistic amount of risk as sort of like a glide path into risk, so thank you.

DR. CROSSON: Thank you.

MS. GRAHAM: Hi. Emily Graham representing the Alliance of Specialty Medicine. Just some really quick

comments about the ACO report.

Thank you so much to the staff and to the Commission for a very thought-provoking discussion. We're really interested in the role of specialty medicine in accountable care organizations, and that seems to be a missing piece of the conversation, quite frequently, in these conversations.

We are very interested in seeing some of the future conversations, what the breakdown of specialty engagement is in accountable care organizations. We've actually been asking CMS for this data for some time, and it's been very challenging to get. So maybe if MedPAC can help with that, that would be terrific -- and also maybe some of the referral patterns.

Thank you so much.

DR. CROSSON: Thank you.

Seeing no one else at the microphone, we are adjourned until 1:15.

[Whereupon, at 12:15 p.m., the meeting was recessed, to reconvene at 1:15 p.m. this same day.]

AFTERNOON SESSION

[1:16 p.m.]

DR. CROSSON: Okay. Good afternoon. I think it's time to get going. To open the afternoon, we're going to return to our issues and potential policy options with respect to payment for Part B drugs. And we've got Nancy, Kim, and Brian here, and who is going to lead off? Nancy.

MS. RAY: Good afternoon. In this session, we are continuing to examine the way that Medicare Part B pays for drugs and biologics under the average sales price system -- ASP. The Commission has been working actively over the last two years on this topic.

Your briefing paper includes details of six policy options, which is the focus of today's presentation.

The first three options -- consolidated billing codes, ASP inflation limit, and a restructured drug acquisition program -- seek to increase price competition among Part B drugs and address price growth. These options were discussed in our recent June 2016 report to the Congress.

The fourth option seeks to improve the current ASP payment formula for Part B drugs, which was also

discussed in our June 2016 report. The fifth and sixth options are new to the Commission. They were recently raised in a prior discussion, and these options look at modifying how Medicare pays for drugs that lack ASP data and strengthening manufacturer reporting requirements for ASP data.

We seek Commissioners' guidance about each policy option so that we can refine them. The Chairman's goal for this coming cycle is to develop policy recommendations for Part B drugs based on policy options of interest to Commissioners. Before moving on, I would like to thank Joan Sokolovsky for her contribution to this work.

You've seen this slide with background on the ASP payment system before.

In 2014, Medicare and beneficiaries spent about $22 billion on Part B drugs. Of that, $4 billion was beneficiary cost sharing and $18 billion was program spending.

Medicare Part B drug spending has grown at an average rate of more than 8 percent per year over the last five years. About half of that growth has been due to an increase in the average price paid per Part B drug.

Most of the drugs covered under Part B are infused or injected in physician offices and hospital outpatient departments. Medicare pays for most Part B drugs at a prospective rate equal to 106 percent of the average sales price.

ASP is the drug's price from the perspective of the manufacturer, and it is based on sales to all types of purchasers with some exceptions, and it is net of rebates and discounts.

So moving to our first policy option, consolidated billing codes. Most single-source drugs and biologics receive their own billing codes and are paid based on their own ASP. The two exceptions of this policy are listed on the slide.

Having drugs with similar health effects in separate billing codes may not always promote the strongest price competition. Your briefing paper includes examples of high-expenditure drugs for which price competition under the ASP payment system has been relatively limited, including products used to treat anemia and products used to treat macular degeneration.

The Commission has held that Medicare should pay

similar rates for similar care. With respect to drugs and biologics, that principle may suggest that Medicare use a consolidated billing code when paying for a reference biologic and its biosimilars and products with similar health effects. Doing so would be expected to generate more price competition among products than separate codes.

So that leads us to the policy option of giving the Secretary the authority to place drugs and biologics with similar health effects in the same billing code and pay them the same rate based on the volume-weighted ASP for the products in the code.

First, this policy could be considered for a reference biologic and its associated biosimilars. Right now, the reference biologic remains in its own code, separate from its associated biosimilars. Under this option, all these products would be included in one code. There is currently one biosimilar that was launched in September 2015 and is paid for under Part B in a separate code from its associated reference biologic.

Second, this policy could apply beyond biosimilars to therapeutic classes in which there are several products with similar health effects. Included in

your briefing material are examples of therapeutic classes for which the individual products are each paid based on their own ASP.

So we cannot give you a direct estimate on the effect of this policy on Medicare and beneficiary spending. Putting products with similar health effects in the same billing code is anticipated to generate savings for beneficiaries and taxpayers. Your briefing materials modeled the effect on Medicare spending by including the one marketed biosimilar Zarxio in the same billing code with its reference biologic Neupogen. Because the payment rate is based on a weighted average, savings would be gradual but would be expected to increase over time as the price of the products decline due to increasing competition.

In terms of issues, to implement this policy for the reference biologic and its biosimilars, the Secretary could rely on the FDA approval process to determine what products to group together.

Implementing this option beyond biosimilars would require the Secretary to have a process to identify drugs with similar health effects. It would be important that

such a process be transparent, solicit input from clinical experts, beneficiaries, other payers and stakeholders, and be designed to avoid conflicts of interest.

During the question and answer period, we are happy to discuss stakeholders' reactions to this policy which is summarized in your briefing materials.

Kim will now take over with a discussion of the ASP inflation limit.

MS. NEUMAN: The second policy option is an ASP inflation limit.

Growth in the ASP+6 payment rates for individual drugs are driven by manufacturer pricing decisions. In theory, there is no limit on how much Medicare's ASP+6 payment for a product can increase over time.

Median ASP growth across the 20 highest expenditure drugs was slower than inflation in the early years of the ASP system, but has exceeded inflation since 2010. For example, in the last year, 10 out of 20 of the highest expenditure Part B drugs have had an increase in their ASP of 5 percent or more.

A policy option that could be considered would be to place a statutory limit on how much Medicare's ASP+6

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payment can grow over time. This could be done by requiring drug manufacturers to pay a rebate when ASP growth for a product exceeds an inflation benchmark. Under this approach, rebates could be shared with beneficiaries by basing the beneficiary's cost sharing on the lower inflation-adjusted ASP.

With respect to provider add-on payments, the 6 percent, there are options for how that could be handled under a rebate approach. They could continue to be based on the reported ASP, or they could be based on the lower inflation-adjusted ASP.

As you'll recall, we've previously talked about other versions of an ASP inflation limit where the providers instead of the drug manufacturers are at risk for price increases. And if you'd like, we can discuss that on question.

An ASP inflation limit would be expected to generate savings for beneficiaries and taxpayers. To get a sense of how much, we simulated the effect of a hypothetical inflation limit policy in 2014 and 2015, using first quarter 2013 as the baseline period from which ASP growth and inflation growth are measured and assuming CPI-U

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is the inflation benchmark similar to the inflation portion of the Medicaid rebate.

Under these assumptions, we estimated rebates would have been about $750 million in 2014 and more than $1.25 billion in 2015. Twenty percent of these rebates would go to beneficiaries in the form of lower cost sharing.

In terms of issues, some stakeholders have asserted that manufacturers might respond to an inflation limit policy by increasing their launch prices for new products.

The third policy option is restructuring the competitive acquisition program for Part B drugs. Medicare implemented a CAP program from 2006 to 2008. Physicians who chose to enroll in that program could obtain drugs from a vendor rather than buying and billing Medicare directly for the drugs. The program faced challenges due to low physician enrollment and the vendor having little leverage to negotiate favorable prices.

Although the CAP program faced challenges, the concept underlying the program -- to eliminate financial incentives for prescribing Part B drugs -- still has

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appeal. An option that could be considered is to give the Secretary the authority to implement an improved CAP program.

In developing a new CAP program, potential goals could include garnering more participation, obtaining more favorable prices, and bringing greater provider accountability for drug spending.

To design a new improved CAP program, decisions would have to be made about a number of issues. We've listed a few of the key design issues on this slide, but, of course, there would be more design questions beyond these. Think of this as a starting point.

The first design question would be: Will the program be mandatory or voluntary with incentives for participation? Will the program include only physicians like the original CAP, or would it also include hospitals? To what extent would the CAP vendors have formulary authority or other utilization management tools? Would the program focus on all Part B drugs or a subset of Part B drugs? How many CAP vendors would participate in the program? And would they be national or regional in scope? And, finally, how would the program be structured

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operationally, for example, a stock replacement model or a GPO model?

So with all of these design questions, there are pros and cons, and to start the discussion, what we have done is put together an illustrative example of one possible approach to answering those questions. Other structures are possible.

First, under this illustrative example of a CAP program, the program could be voluntary with incentives for participation. Providers could be offered the opportunity to share in any savings from the program. At the same time, the ASP add-on percentage could be reduced in the buy and bill system, making it less attractive.

The program could include both physicians and outpatient hospitals so that there is a level playing field across these providers.

To give a CAP vendor negotiating leverage, the vendors could be permitted to operate a formulary.

Fourth, the program could be used selectively, focusing on a subset of drugs where the management tools available to the CAP vendor would be expected to yield the most savings and where the administrative complexity of

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operating the CAP program is the most straightforward.

The model could involve multiple CAP vendors to give providers a choice of which entity to work with. And the vendors could be regional in scope to facilitate more local input into the formulary development process.

Finally, the CAP program could structured as a stock replacement model to avoid some of the difficulties the original CAP program encountered with physician advance orders.

In terms of the implications of a restructured CAP program, a redesigned CAP with effective management tools and appropriate incentives is expected to save money for beneficiaries and the Medicare program. The amount of savings would depend on many factors, such as which drugs were included, the amount of provider enrollment, how much the ASP add-on is reduced in the traditional buy and bill system, and the extent of formulary authority.

In terms of issues, in recent site visits and interviews we conducted with a sample of oncology providers, we heard concern from some providers about administrative burden associated with a CAP program.

Some of those concerns related to the logistics

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of ordering drugs from a CAP vendor, particularly the requirement in the original CAP program that physicians place a patient-specific order with the CAP vendor in advance of each patient's visit. Modifying the CAP program to be a stock replacement model or, alternatively, a GPO model could help address that issue.

Some providers also expressed concern about the CAP program only applying to their Medicare patients and stated that it was burdensome to operate two different drug acquisition systems -- one for a Medicare CAP program and one for other payers.

Finally, we note that a new CAP program would require the Secretary to develop the program parameters, operate a competitive bidding process for vendors, and then oversee the selected vendors' activities.

Next we have a policy option to modify the ASP add-on. As we've discussed, the 6 percent add-on to ASP may incentivize use of higher-priced drugs, although few studies have examined this issue.

In the June report from 2016, we obtained proprietary data from IMS health on invoice prices for the clinic channel of purchases for 34 high-expenditure Part B

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drugs. We found that for two-thirds of the drugs, at least 75 percent of the volume was sold to clinics at an invoice price of less than 102 percent of ASP as of first quarter 2015.

In the June report, we modeled an option to restructure the ASP add-on into a hybrid percentage add-on and flat fee. That option was 103.5 percent of ASP plus a flat fee of $5 per drug administered per day. That option would structure to save about 1.3 percent assuming no utilization changes. And under that option, add-on payments increased for drugs with an ASP per administration of less than $200 and decreased for more expensive drugs, with the effect being that the policy option lessens the difference in add-on payments between high-cost and low-cost drugs.

So last cycle, Commissioners expressed interest in modeling additional options, so we are coming back to you with those now.

First, we have the hybrid option from June that I just talked about.

Second, we have something we're calling a modified hybrid. Some Commissioners expressed concern that

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the $5 flat fee add-on under the hybrid option increases add-on payments substantially for very inexpensive drugs. And so the second option address that concern by setting the payment at the lesser of the hybrid or 150 percent of ASP.

Your paper contains another version of a modified hybrid option that limits the add-on payments for inexpensive drugs even more. For clarity of presentation, we are just presenting this one option here, but I'd be happy to discuss the other on question.

Third, we have an option that keeps the ASP add-on formula as is, but takes one percentage point off, so 105 percent of ASP. The idea here is to keep things simple while achieving modest savings.

Recall like in the June report these options refer to the pre-sequester payment rates. With the sequester, provider payments would be about 1.6 percent lower.

In terms of implications, all of these options would generate savings for beneficiaries and taxpayers. The revenue effects of various options vary across

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providers, and I will show you those numbers in a moment.
All three options lessen the difference in add-on payments between high-cost and low-cost drugs to varying degrees. For example, the hybrid reduces the difference in add-on payments between differently priced drugs by 42 percent; the 105 percent of ASP option reduces the add-on difference by 17 percent. On the margin, a smaller difference in add-on payments across differently priced drugs might increase the likelihood that a provider would choose the least expensive drug in situations where alternative products exist.
In terms of issues, some stakeholders assert that reductions to the ASP add-on could contribute to the trend toward more hospital-based care.
So here we have some numbers on the effects of the various options. We've modeled the options using 2014 data, and for estimation purposes, we assume no change in utilization.
Program and beneficiary savings are shown in the first two rows. In the first column, the 105 percent of ASP option has an estimated annual savings of roughly $190 million, $150 million for the program and $40 million for

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beneficiaries through lower cost sharing.
The hybrid option in the middle column saves more, roughly $270 million for the program and beneficiaries. And the modified hybrid option on the right has the highest savings estimate, roughly $355 million.
The reason savings are higher under the modified hybrid is that very inexpensive drugs (in this case, drugs with an ASP per administration of less than $11) don't see as big an increase in their add-on payments under the modified hybrid as they do under the hybrid.
Looking at the distributional effects in the bottom of the chart, we can see in the first column that the 105 percent of ASP option has a uniform effect across all providers -- about a 0.9 percent reduction in their Part B drug revenues.
The effect of the hybrid (in the middle column) varies across providers depending on the mix of drugs they use. Specialties that tend to use expensive drugs see a decrease in their Part B drug revenues while those that use less expensive drugs like primary care see an increase in their Part B drug revenues.
With the modified hybrid, the effect is similar

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to the hybrid except that the add-on payments don't increase as much for inexpensive drugs. And if you look at primary care, you can see that. So under the modified hybrid, primary care's Part B drug revenues decline; whereas, under the hybrid, they increased.
Now I'll turn it over to Brian to discuss drugs paid based on wholesale acquisition cost.
MR. O'DONNELL: Our next issue is drugs that are currently paid at 106 percent of wholesale acquisition cost or WAC+6. Wholesale acquisition cost is a drug's list price, and unlike ASP, does not incorporate discounts. Drugs are often paid at WAC+6 when ASP data is not available. For example, a new, single-source drug can be paid at WAC+6 for nearly three quarters, because ASP is based on the first full quarter of data and there is a two-quarter lag due to data reporting.
Because the data used to set a drug's initial ASP is based on data from when a drug was paid at WAC+6, we analyzed how prices changed when drugs transitioned from being paid WAC+6 to ASP+6 for a subset of new, high-expenditure, Part B drugs.
For the drugs studied, we found that modest price

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declines were common. This suggests that discounts were present when these drugs were paid at WAC+6, and that Medicare and beneficiaries paid more than if the drugs were paid at ASP+6. Therefore, a policy option for the Commission to consider is reducing Medicare's payment rate to WAC+4 percent.
Additionally, if the add-on payment for ASP-priced drugs is changed, a commensurate modification to WAC-priced drugs could be made. For example, if the ASP add-on is changed to 5 percent, as Kim discussed earlier, then lowering the price to WAC+3 percent would maintain a rough parity between WAC-priced drugs and ASP-priced drugs.
In terms of spending implications, it's difficult to precisely estimate the savings associated with this policy, because there is often a lag when a drug can be billed under Part B and when a HCPCS code is assigned, which makes tracking utilization difficult. However, we expect a savings to be modest and to vary based on a number of factors, such as the number of new, single-source drugs introduced in a given year.
Our last issue involves manufacturer reporting of ASP data. Currently, only manufacturers with Medicaid drug

rebate agreements in place are required to report ASP data. For example, the OIG found that at least 45 Part B drug manufacturers were not required to submit ASP data in the third quarter of 2012, although some did voluntarily.

Therefore, a policy option for the Commission to consider is requiring all manufacturers of Part B drugs to report ASP data. This policy could improve data accuracy in general. It can also be viewed as complementary to other policy options under consideration. For instance, universal ASP reporting helps ensure the inflation limit policy discussed earlier has the appropriate data needed for implementation.

Finally, please let us know if we can provide any clarifications on any of the six policy options we discussed. And given the Chairman's interest in moving towards draft recommendations, we are seeking the Commission's feedback on which of the policy options to pursue, and within the policy options, preferences on design choices.

And with that I turn it over to Jay.

DR. CROSSON: Thank you very much. Very clear. A lot here.

We're going to do clarifying questions. I'd like to start with one, on Slide 16. So -- and I guess Kim, the numbers we see here, in terms of reduction in revenue, don't necessarily, or wouldn't necessarily translate, at least over time, into reductions in, let's say, the bottom line for physicians, because there are potential behavioral responses here. There's some empirical evidence, I think, that, at least in the past, there's reason to believe that the drug companies might, in fact, reduce how much they charge the physicians as a consequence of one or more of these changes. And, in addition, there are potential behavioral changes by the physicians themselves, based upon a changed set of incentives.

Do you want to -- is that -- have I got that sort of right? If I don't, say.

MS. NEUMAN: No. I agree. I agree with both points, yes.

DR. CROSSON: Okay. Thank you.

Clarifying questions? Okay. Kathy, Bill, Rita.

MS. BUTO: Jay, do you want us to ask clarifying questions about all six?

DR. CROSSON: I'm sorry. Yes, about all six.

MS. BUTO: Okay.

DR. CROSSON: What's been presented.

MS. BUTO: Okay. So I'll try to be quick. So my question -- first, I would be interested, just overall, if you could kind of give us a sense of which are the biggest savers versus -- you know, even though you don't have precise numbers and consolidated codes, versus those that may have less of a savings associated with them. So that would be question 1.

Secondly, on consolidated codes, I didn't hear you speak about it, and I don't think we've talked about any kind of appeals process there. Appeals process is a little bit of a strange concept because we're setting a payment rate, but we know it's a payment rate that's below the cost of several of the drugs in a category. So I would just say do you see any circumstances where that might be considered, or is it something that you thought about?

And let me just go through my questions and maybe we can --

DR. CROSSON: Just one question on that, Kathy. Are you talking about appeals by beneficiaries or appeals by drug companies?

MS. BUTO: By beneficiaries.

DR. CROSSON: By beneficiaries. Okay.

MS. BUTO: Yeah. Presumably the physician could prescribe whatever the physician prescribes if he or she is willing to absorb the added cost of a higher-cost drug in that category.

On the ASP limit, I'm really curious about -- I understand that we've come down on the side of taking the rebate approach as opposed to taking the approach of limiting the Medicare payment, which, you know, in other words, not -- for Medicare not to recognize the price increases, but, in fact, to get the rebate from the manufacturer. And you can make the beneficiary whole, and you do make the physician whole -- we would make the physician whole. I'm just curious because if we limited the Medicare payment, it seems to me we do have the opportunity to have a simpler application of the limit, and it's more straightforward for the beneficiary and for the program to realize those savings.

And sort of related to that is, it's -- I think it's complicated but maybe you could speak to how complicated it would be for CMS to follow the data lag, and

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price increases, and price decreases, and then vary the copayments for the beneficiaries. I mean, there's a lot of behind-the-curtain kind of work that has to be done to make this work. So I'd just be curious, your comments on that.

And then -- let's see. I think I have one more question about the ASP add-on. Why not -- why it shows -- I think I now understand it better -- 150 percent of ASP as the hybrid option for the low-cost drugs, versus 106 percent, which would have been the lower of the new policy or the existing ASP+6 percent. I think the answer is it really its primary care harder, but it might also -- and I'm just guessing -- relate to our interest in promoting the use of more cost-effective drugs. So that question, why did we go to 150 versus 106.

And that's it.

MS. NEUMAN: So I think that we have a difficult time telling you which option would save the most. Where we have been able to estimate initial figures, we've done so, and some of them are much more speculative and things that happen in dynamic processes over time. And so to try to speculate about what that steady state might be is pretty hard. We can go back and think if we have more ways

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to put numbers around it, but at this point I don't think we could -- we can say more than we have, about the relative savings of different approaches.

I'll skip to the ASP inflation limit and do consolidated at the end?

MS. RAY: Yeah.

MS. NEUMAN: Okay. So on the ASP inflation limit -- so there's a policy choice, right, about whether you want to do it through a rebate or whether you want to limit the provider payment rates, and a big part of that choice, for you all, if you pursue this kind of a policy, is sort of who will bear the risk, whether it will be the drug manufacturers or the providers, and that's just a question to decide on.

The second piece about complications, in the rebate approach, when you are reducing the beneficiary's cost-sharing to allow them to share in the rebate, you are effect -- what you would effectively be doing is setting the beneficiary cost-sharing at the rate that it would be if you had a payment limit in place, that alternate policy. So there's no difference in work on that piece for CMS, for a rebate versus the provider payment limit approach.

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Now, on the other side, they would have to collect rebates, right? And so there is extra work in that piece. But on the beneficiary cost-sharing, I think it should be the same process, regardless.

MS. BUTO: Assuming that the cycle of drug pricing changes follows the same cycle as a payment rate change might follow. Say, you know, quarter to quarter or whatever it is, annually.

MS. NEUMAN: Right. I mean, you would have to -- like in Medicaid there's this lag where you're going at look-back periods where you have data available. And so if you could set it up similar to Medicaid, we should be able to keep it tracking pretty well for the single-source drugs, I think. But we can go back and think more about that.

DR. MILLER: What you were saying was that basically every time CMS publishes the ASP they would just have the ASP, and they would know an inflation-adjusted ASP, and they would say "and the benes cost-sharing is X." I mean, they have to derive the number, but the signal and what they put out on the street, on a quarterly basis or whatever, should be relatively calculatable.

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MS. NEUMAN: Right.

MS. BUTO: Yeah, except that ASPs can also go down. They don't always go up. So that -- that calculation would still occur. It's just that it gets into the collecting of rebates and copays, and it's not as -- it sounds straightforward but it's not as straightforward, I think, from a systems perspective as that sounds.

DR. MILLER: I hear that. I think -- and Kim hit this point -- but I think the other conceptual consideration that you guys have to discuss is if you say that the provider is at risk, what you're basically saying is the ASP has said here, and if the inflation rate goes above that, Medicare is paying below that amount and the provider is bearing the risk. Alternatively, if you say the -- if the rebate method, the provider gets the higher amount and then the manufacturer has to make the program whole. And I think that's the discussion that you guys should talk through, about who bears the risk.

MS. BUTO: And we'll get into this in Round 2. But it's not just the -- let me just turn that on its head. The provider isn't not bearing the risk. The provider is actually being made whole. So the provider's incentives

really don't change at all. There's still some incentive for the provider to pick the highest cost drug in -- you know, even with the price increase, because they get -- they're made whole by the program, both for the copay and for the total price.

So I'm just ask -- exploring that issue, because it's not just that they would have to bear a risk. Right now they're being made whole. So I just wanted to make that point. And the beneficiary hopefully will be made whole.

DR. CROSSON: I mean, this is Round 2, but Kathy, that also assumes that this particular option is the only one on the -- that is executed in the end, because there would be other incentives for the providers to choose less expensive drugs, arguably.

I'm sorry. Sorry.

MS. NEUMAN: And the other question was about the -- why -- which -- why we presented one modified hybrid versus the other, the capping the add-ons at 150 percent of ASP or 6 percent of ASP, and again, that's a policy choice that you can decide between, if you go that route. There are pros and cons to the various approaches. I will just

say, about the 150 percent of ASP cap, the idea there was that the hybrid was intended, or had some motivation, in lessening the difference in add-on payments between higher- and lower-cost drugs. And so the 150 percent of ASP option allows the lower-cost drugs to still get a bit of a bump, whereas the 106 percent option does not.

So just, you know, one reason why we thought about that. But there is a choice there.

And then consolidated billing.

MS. RAY: Right. So you had a question -- did we envision an appeals process, and I think that's a policy choice that Commissioners could choose to discuss in Round 2.

I guess what I would say about it is, I guess, the situation where the provider's acquisition cost is lower than the Medicare payment rate for a given consolidated billing code, I think that would vary from product to product and be hard -- would, of course, be dependent upon the manufacturer's response to the policy.

I will say that in the one situation where two products were -- I have -- there is a situation with the ESRD payment bundle, when it was started in 2011, with the

two vitamin D products. You saw increased competition. You saw prices going down between 2010 and 2015. And you still did see utilization with the higher-priced product. Again, it's not a quite apples-to-apples comparison. It's the best comparison I can give you at this point.

MS. BUTO: Thanks.

DR. CROSSON: Bill.

MR. GRADISON: On page 13 of the mailing, there's a sentence which refers to the development of competitive biosimilars, and it says that manufacturers who wish to do this are able to produce a similar product at lower cost. It's the lower cost question. Is that true? Are you sure that's true?

The reason I ask is it's been so slow to see some of these things come along, and they're not chemically identical, that I just want to make sure you -- whether -- accept whatever you say, except I just want to make sure.

DR. MILLER: So, I mean, what I would say is we've talked to a bunch of people, okay, and that's a scientific term.

[Laughter.]

DR. MILLER: And we -- for me, anyway, I don't

know who's on point to answer this, but -- if it's Nancy. I mean, my takeaway from those conversations -- and anybody else over in the D crowd that wants to speak up -- you know, my take is we've heard, yeah, you're going to get discounts but the discounts are going to look like this, and I've heard, you know, yeah, you're going to get discounts and they're going to look like this. And I think, you know, big.

And so my takeaway from those conversations is, yeah, you're going to see discounts relative to the referenced drug, but whether they're going to be large or large in the near term, I think, is --

MR. GRADISON: That's not my question. My question is to the cost of production.

DR. MILLER: I think their starting proposition -- I'm sorry. That was implied in my answer.

MR. GRADISON: Okay.

DR. MILLER: The starting proposition is that they do think that they can bring some efficiency to the production. Remember, they're trailing on a reference drug's, you know, development costs.

DR. CROSSON: Okay. Next I have Rita.

DR. REDBERG: Thanks for an excellent chapter, and a lot of options.

My question -- clarifying question was on Table 1 in the mailing materials. I'm interested if you can give us any more detail about those drugs, and the questions I have are do you know how much of the use there was on- or off-label? And then I have two more.

MS. NEUMAN: We haven't tried to break this down by on-label versus off-label, not to this point. That is a tough one.

DR. REDBERG: Yeah. I don't think -- and also related to that table, do you know how many of these would be called "me, too" drugs as opposed to first-in-class, or whatever we call them? Again, you can come back to me with this. I don't expect any of these you would have at the tip of your fingertips.

And the last one on that table was, do you know how many of these have generics available, or are generics?

MS. NEUMAN: I think that the only one that's generic is capecitabine, if I'm -- at least in this time period.

DR. REDBERG: Okay. Thanks.

DR. CROSSON: Okay. Other clarifying questions?

Bruce.

MR. PYENSON: Thanks very much. I think this is a question for Kim on page 16. The various savings there, is that extrapolated to Medicare Advantage plans as well, assuming that the reductions would be built into the benchmarks?

MS. NEUMAN: No. This is just a pure change in fee-for-service payments.

MR. PYENSON: Thank you.

DR. MILLER: This is off of a $22 billion base? Is that what we're talking about here?

MS. NEUMAN: Right.

DR. MILLER: Okay.

MS. NEUMAN: In that neighborhood.

DR. CROSSON: Okay. So now we're going to start the discussion period, and I would like to divide the discussion into two parts. So we'll try to have two Round 2s, and for the first one, we'll take the first five options, and then the second round of discussion will be on the cap.

As has been mentioned, we have a lot of pieces on the table here. The cap option itself has, as you saw from

the presentation, a number of design options inherent in that. In order to keep the discussion sort of organized, let's take comments on the first five in the first round, and in general, in both parts, in both Round 2 discussions, let's go, as best we can, to what we strongly disagree with, we'd like to take off the table, but increasingly, importantly, as we move through this, what we do agree with, and to some extent and as concisely as possible why.

Jack, you're going to start off the discussion.

DR. HOADLEY: Thank you, and thanks to the staff for great staff work in developing and beginning to sort of narrow and target out list of options. I think we're at a point where we really have a good set of ideas to work with, and what I think we have is an array of tools to give to both Congress and CMS, options that can potentially exert some downward pressure on drug prices in this sector and costs for the program, while as best as possible avoiding consequences, negative consequences for access and sort of other issues.

So, I mean, I really do think overall, this set of tools has the potential to meet these goals. In my view, we've got a set of tools that are mostly not in

conflict with each other that could all exist, coexist as options, and they're mostly not interdependent, at least not in the way we talked about last year with the Part D tools, where a number of Commissioners really emphasized and our report emphasized the notion that we really viewed it as a package of things where items here sort of wouldn't work unless another item was done.

I think that's not so much the case here. I think each of these may address different pieces of the pricing issue. Together, they may, in fact, create something of a package that addresses a little bit here and a little bit there, so inflation comparison of similar products and so forth, but they also could be used alone. The partial exception -- and, obviously, we'll get back to that -- is the cap, which in some ways is just a different approach, and we'll get to that in the next Round 2.

To go specifically on the five, I guess I would -- just following down this list, I like the consolidated billing codes option because of the way it's sort of trying to get it averaging, the pricing for similar drugs. In my view, it's most effective and maybe should be really mostly focused on the biosimilars, and while we don't have a lot

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of those cases today, we think we will have quite a few of them in the relatively near future.

The reason I say that as opposed to some of the therapeutically similar drugs is, I think, as was the case in some of the previous policies that exist, that I think in the drugs that are therapeutically similar going to become a constant sort of political fight. So, if somebody says, "Well, these two are going to be put together in one code," providers, manufacturers, patients, whoever, are going to say, "No, that doesn't really work for me." It's going to get challenged in court or politically or whatever, and I think in the end, the chances of having a lot of successes along those lines will be slim, potentially, or at least less than in the biosimilars. In the biosimilar, we at least have some FDA type of certification that these drugs are supposed to do the same thing. So I wouldn't necessarily rule it off the table for the others, but I think our focus in this case, I would put on the biosimilars.

On the ASP inflation limit, I like the choice of the rebate approach. To me, that does work better. It's the manufacturer who is the source of the higher price, and

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so that puts the burden or the adjustment on the manufacturer. And we could get into the details that Kathy was raising, but I think those are all workable along the lines that you guys have already said or some other thoughts that I could offer on that.

But I do think that it addresses, again, something that we know is a problem, where the prices of these drugs go up, the idea that one of the issues is will this affect launch price. Well, I think there are already plenty incentives to set launch prices high.

We've got the same issue on the Medicaid rebate side: Does it create incentive? Yes, it probably does create some incentive, but there are lots of other things that create the incentive. So I don't think it really sets us back very far. So I think that's, again, something I like.

The modification of the add-on, again, it's an approach that I like. I'm not fully convinced about my choice among the three alternatives or the four alternatives. I think the straight reduction to 105 percent is my least favorite. I think I probably -- right now, my most favored is the modified hybrid approach that

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you had up there for the kinds of reasons that you talked about, but I don't know that to me it's an absolutely clear-cut case, at least between the two, the hybrid and the modified hybrid.

And I think part of what we may want to do in that is, in the chapter, whatever, assuming we come down and make a recommendation on one particular approach, if we talk about the other approaches, we're also offering policy-makers the ideas because, again, they use our guidance sometimes for doing exactly what we say, and sometimes it's just a starting point for a conversation.

So we've already served a value in saying that amongst a variety of approaches, you get these differential effects, both dollar-wise -- I mean, I think the table that was on Slide 16 is just something that will be valuable, even if we end up saying -- and we've settled as our primary recommendation on this one particular option.

And then the last two, the WAC and the ASP data reporting, I think, are both good ones. My sense is, to Kathy's question, these probably have the least dollars involved of the five, but they're good fixes. They are

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problems that are out there. What happens in the first year for a new drug? What happens with some of the gaps that we've seen in -- I guess it's either OIG or GAO, as you cited, did a recent report on that, on the data reporting issue. So I think those are good problems for us to identify. Those should be relatively noncontroversial in this discussion.

So I think the choices really are on the inflation limit, the billing codes and the add-on, but I think the way you've laid out options puts us in what I think is a good position to do some good things. I think we're making good progress on this.

DR. CROSSON: Thank you, Jack.

Let me see hands for Round 2, Point 1. Okay. We'll start with this way, this time, and come around that way. Amy, you're first.

DR. BAICKER: Again, thank you. It was a wonderful chapter and very thought provoking. I have comments on all of these options.

So, unlike Jack, I actually, with respect to consolidation, think that we should not put biosimilars yet in the category of the innovator product. We're all

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anticipating a robust biosimilar category, but we're still not there.

My fear is that those that are bringing biosimilars forward really are also those that are makers of innovator products, and if we provide too much disincentive for them to continue to invest in this area, we're never going to see the market that we anticipate.

So I think it's a good idea. It's probably also intuitive. It's, in my opinion, too soon. We need to have this market and then readdress this.

I think there are plenty of ways for us to establish consolidation of those that are therapeutically interchangeable or PBM to this today. We have process for determining how ACE inhibitors or a beta blocker or a pick-your-favorite-category are lumped together or are preferred one over another, and so we can use those best practices. We don't have to reinvent the wheel here. So I think that there is a pathway forward.

I'm in favor of a base provider add-on payment on the lower inflation-adjusted ASP. In doing so, I wouldn't offer an appeal process. I think when you look at what pressure that would put on the other products in the

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category, what manufacturers are going to respond to is market share.

If providers aren't prescribing product because they're losing money on them, ASP will come down on those products that are inflated. They will, in fact, respond to the fear of loss of market share. So I think in and of itself, it will solve for itself, and not every single product needs to be a profit center for a physician. You make a lot of money on some; you might lose some money on -- - I don't think they all have to be in the black, if you will.

I think we need to think long and hard on the add-on. I like the hybrid because of what it did to primary care. We had a discussion last month about what about primary care. Maybe this is one way to help the primary care physician. While not costing Medicare any money, we're still saving, and so maybe there's something there I'd like for us to explore further.

I'm in favor of WAC+3, not 4, and I'd like to understand Jack's point about those products that are new to market. What happened to, say, the Sovaldi when it was -- maybe that's not the best example, but these high-dollar

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products when they first come out. I think the future is in specialty. I do fear that if we don't have something aggressive out of the gate, you have a perverse incentive to prescribe these products where you're making a ton of money, and your data proves that, that WAC+6 is far out of market in comparison to ASP.

And, lastly, I would require all manufacturers to report ASP, so that then we can -- we can, in fact, implement some sort of inflation protection. I think inflation protection tied with the pressure on the reimbursement to provider is important. You can't just push on one of these areas. It just balloons in another area. You've got to take them all on in concert.

So I think they all are doable. I wouldn't say no to any at this juncture. Thanks.

DR. CROSSON: Thank you.

Coming up this way, David.

DR. NERENZ: Thanks. This is a question focusing mainly on the issue of modifying the ASP add-ons and a question to my clinician colleagues here.

The estimates we have on Slide 16 are based on an assumption of no change in behavior, and that's okay. I

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understand why, because it's pretty speculative.

My question is really about how confident are we going forward with that assumption. It seems like when we got into this discussion many months ago, focus on the ASP+6, we have the view that the +6 created an incentive to prescribe more expensive drugs, and there was a little bit of evidence for that.

Now, here, the actions we're talking about sort of weaken that incentive a little bit. They don't make it go away because you still make more money with more expensive drugs.

My question, though, is what other options might there be if these financial incentives actually matter? And I'm thinking of oncology, and I know you folks know oncology as well too. Right now, if you prescribe two drugs for a particular regimen, perhaps you could prescribe three drugs if the APS+something goes down, and then one of them has complication effects. And so now you need to prescribe antiemetic, and now you need to prescribe white cell-promoting factor. Is it reasonable to be worried about those behavior changes, or on the other hand, are things so protocol driven, so guideline driven, so other

quality metric control that that won't happen?
DR. CROSSON: On this point, Rita, go ahead.
DR. REDBERG: As David's clinician colleague.
[Laughter.]
DR. NERENZ: I did have you as one of those in mind.
DR. REDBERG: I was just struck. In particular, I was on a committee last week where an oncologist commented that he thinks a substantial percentage now of oncology drugs are overprescribed and that people would -- inappropriate. And there isn't any kind of recognition of that in this, and I don't know if it's in the bundle. But I'm just trying to think of -- because before you take on price, the first question is, Are patients better off getting these drugs or not? And some of these drugs, clearly the answer is yes, but some, the answer is no. And there isn't any way -- I would think that would ideally be the threshold question.
And I don't think we'll necessarily get it with on-label or off-label, and as you know, there's a lot of questions for oncology, which is one of the big ones, about why Medicare has to pay for everything in an NCCN

compendium, which is not an evidence-based compendium and has a lot of conflict-of-interest issues with the people that write it.
So I think, getting to the clinical questions, first, ensuring some kind of appropriateness before looking at sales prices would really be a win-win for beneficiaries and for the program.
DR. CROSSON: Alice.
DR. COOMBS: So, David, you asked a very good question: Is the field of oncology pretty amalgamated into a similar type of protocolized peer? And what you find is that you can be in Rochester, you can be in Boston, but the protocols are very similar.

What would happen, I think, with some of the reduction in terms of the plus whatever is that -- and it's happening right now -- is that if the provider is dependent upon X for overhead and X for this, that it may reach a critical point where -- and many regions, as in the Southeast region, many oncology practices are purchased by the hospital, so it drives the oncologist to have a hospital-based program.

Now, what does that do for the cost of health care? It drives it up astronomically. So that the unintended consequence with much of what we talk about in terms of the add-ons is really considering what's going to be the tipping point, such that oncologists will say, "You know what? That hospital job looks very attractive," and so that's going to actually affect access and has in some regions where oncology practices have been bought out by hospitals, and therefore, the focus for which they practice, they leave a community. So on oncology group leaving a community leaves all of those beneficiaries there to scramble for the next nearest cancer center. And when they get to that cancer center, there are all the facility charges, which are much greater on a hospital basis situation -- and we studied this in MedPAC -- than if they were to go to the doctor's office and they were to have their agents administered to them in a hospital setting. So that's the big unintended consequences is how it impacts access, purely because the cost of doing business in oncology may become so unbalanced and then the barriers for them to the practice.
DR. CROSSON: Brian.

DR. DeBUSK: First of all, I like all of the ideas that were presented today, and I think there's some really exciting options. So, just for the record, I'd like to support all of the options that the staff presented.
Walking through the first three, when you look at the consolidated billing codes, I think that's a very easy option to support because it does support our principle of paying -- of Medicare paying similar rates for similar care. I think that's something that's nonnegotiable.
I also like the ASP add-on restructuring. I think for reasons that have been cited earlier that the modified hybrid is an excellent way to go because I do think it buffers primary care a little bit.
And then, also, I like the inflation limit. I think those first three options work very nicely together, and I really hope that we get to bring them forwards as a package.
Now, in terms of the WAC markup and the mandatory ASP reporting, to me, I see that -- and maybe I'm mistaken here -- I see that more as a launch issue. I think any markup that we apply there to WAC should be uncomfortable.
I think, Amy, are we at WAC+3 now? Well, I'll

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raise you to WAX+2 or WAX+1. I think when you look at mandatory reporting, I think we should make mandatory reporting mandatory, but I also think we've got an opportunity here if we'll set the markup when we're using WAC to an uncomfortable level. Then we can let them come to us with the numbers because I don't think it should be incumbent on us to chase those numbers down. And I think at WAC+0 or WAX+1, I think they'd probably be willing to bring some ASP data to us.

Thank you.

DR. CROSSON: Thank you. Very clear.

Alice, on this point?

DR. COOMBS: Yes. I just forgot to give my laundry list too.

DR. CROSSON: Oh, okay.

DR. COOMBS: So I would say I agree with the consolidated billing codes, the ASP inflation limit, because it puts less risk on the provider and more risk on what we want to do in terms of the bulk of the cost driver for pharma in this area.

I would agree that if we were going to do an add-on, probably the hybrid might be a reasonable place to be,

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although I'm not enthusiastic about the add-ons.

And the data reporting, I think is -- I agree with that and support that.

DR. CROSSON: Okay. Pat.

MS. WANG: I really like Brian and Amy's approach towards the WACs. I think those are very good observations, coupled with data reporting. I'm not so sure about consolidated codes. That sounds like -- of all of the options, which are great, that's one I'm the least certain about because it sounds a bit complicated. I'm not sure the lemon is worth the squeeze, I guess.

The only other thing, at least at this point in time, in terms of the inflation limit and modifying the add-on, I would say that to me those two things should go together. This could be just like, you know, you pick this one, this -- I don't view them as all independent actors. I think the inflation limit addresses cost of the product, and the add-on addresses the incentive issue that people are concerned about. So I would put them together. I'm not sure that I care so much about whether it's a rebate or whether it's, you know, the product price or what have you, as long as the beneficiary is sort of held harmless there.

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But that's the only gloss I would put on that.

DR. CROSSON: Thank you.

DR. GINSBURG: Sure. A couple of thoughts. I think I'm inclined to go in Jack's direction on the consolidated billing. I'm thinking it's more appropriate for biosimilars. And, actually, it seems to me that this is going to be a boon for biosimilar manufacturers because, you know, we're really boosting the incentive for physicians to choose the biosimilars. And it's not really interfering with what they're charging for. They'll do very well.

It seems to be a very strong tool for other, you know, potentially therapeutical substitute drugs, and so I think we have to be -- this just may be a stronger tool than we really think it is, and it's worth thinking through.

I'm fine with the inflation limit. I think the inflation we're seeing in single-source drugs is a reflect of the change in the demand environments, that, you know, you can get a higher price now than you could have gotten when you launched because so many fewer patients are being prevented from paying the higher price because now they

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have more than recovered. They have out-of-pocket limits. And I think there's nothing wrong with -- I mean, I think there will be an offset in somewhat higher launch prices, but I think it's still worthwhile doing.

One concern I have with modifying the add-on is that I'm glad the presenters mentioned that, you know, we have the sequester, and what we mean is that we're really talking about closer to starting off with ASP+4. And it means that unless we go to the Competitive Acquisition Program, we probably are going to put some physicians in the position of guaranteed loss on expensive drugs. And with Alice's comment about driving them into hospital practice, you know, I think I'd want to be very cautious about that.

I do like the modified hybrid as probably the best way to go on it, and I don't know how long the sequester lasts. I guess indefinitely.

[Laughter.]

DR. GINSBURG: But, you know, maybe we should start assuming that because of that we just don't have as much room to innovate on the add-on because the add-on is a fact of life much lower than it used to be.

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DR. CROSSON: Thank you, Paul.
DR. HOADLEY: Can I follow on that?
DR. CROSSON: On that point, Jack?
DR. HOADLEY: Yes. Briefly, one thing to think of on that is, as the staff has presented, you know, we saw a price response from the manufacturers to the original sequester, and so in some ways, that is part of -- that's got to be thought of as part of the context, and since part of what this policy option would hope to create or could potentially lead to is, again, a price response from manufacturers. So I think that's just part of the story around how we think about that.
MS. THOMPSON: I'll be brief. I remain interested in learning more about Amy's concern about the consolidated billing code. Initially, I leaned toward thinking that was good, but I would just be interested in her subject matter expertise around that. So I would reserve comment.
On both of the items around ASP, I also am concerned about the unintended consequences of what would happen in terms of -- because I think in today's world, oncology protocols look pretty similar, as you pointed out.

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Is there something that would happen if we mess with that? I'm not sure. But on the WAC+6, 5, now down to 1, I'm with you. And data reporting, absolutely.
DR. MILLER: Did you say anything about the inflation?
MS. THOMPSON: [off microphone].
DR. MILLER: Okay, like Pat was saying.
DR. SAMITT: So I'm comfortable with four of the five. The one that I am least comfortable with actually is modifying the ASP add-on. And I'm uncomfortable because I don't know if these changes are going far enough or going too far, because what I'm worried about that one is that, you know, there are potentially perverse incentives associated with the ASP plus anything, either because it could influence excessive prescribing or it could influence prescribing of lower-cost alternatives. And so I know we're not supposed to talk about the CAP, the Competitive Acquisition Program, but I would vote for the four of the five, with replacing the ASP add-on with the CAP.
DR. CROSSON: Thank you.
DR. HALL: Okay. I think there are merits in all of the plans, and I just want to make kind of a side

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comment to it, that this is an area where there is significant physician discretion on which drug to use and, where there are similars, how to move in one direction or the other. At the same time, there is a burgeoning field of clinical guidelines in many of these things, which doesn't really enter into all of this, so there is a whole other aspect of this that might help rationalize the process if we also point out that the clinical guidelines are developed or will be developed as these various agents come forward, and that that should be part of any decisionmaking on the payment side.
DR. MILLER: Did you have views on the specifics?
DR. CROSSON: He said he supported all [off microphone].
DR. MILLER: Oh, he did? I'm sorry.
MR. GRADISON: Overall I would not raise questions or object to any of these, so long as the context is that we're giving a range of options and not recommending any over others. But that may be a discussion at another time.
I specifically want to say a word about the ASP inflation limit. I think it could be counterproductive in

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the sense -- let's take a hypothetical. If the limit was the most recent ASP plus 10 percent, that's a pretty powerful incentive to increase your price 9.9 percent, because if at the end of the second year you haven't increased your price at all in the first year, you can't go up 20 percent. You're still limited to 10 percent in each separate year.
Let me give you an analogy. Under the Affordable Care Act, as I understand it, if a premium increase is 10 percent or more, there is an enhanced review of it I believe required at the state level, and if they don't do it, I guess the Feds do it. I think that's my understanding of how that provision works. Nowadays that seems quaint because so many of the increases are well above that. But a year or so ago, people were saying, well, we can already see it in some states because they're coming into the state insurance commission with a 9.9 percent increase. I think you have to watch this, how it might affect pricing behavior.
My other point has to do -- I have a solution to the difference of view between zero up to six, which is simply by the end of the third quarter, at least -- I guess

actually by the end of the second quarter, data would become available with regard to the actual ASP. Why not just go back -- and call it a "clawback" or whatever you want, but go back and readjust those earlier quarters by what was the actual ASP during the first and second quarter, which you didn't know about at the time because of the time lag. I think that is fair. You don't get into the question of behavioral impacts particularly. And I'd just ask that in thinking about -- I think I explained enough. I don't know whether "clawback" is the right term, but something of that kind.

Finally, on the inflation adjustment, I think I know the answer to this. I'm not asking for one now. But the assumption when we use that terminology is that there will be inflation and the prices are always going to be going up, which may be true, although I don't think it is in every case. I'm not entirely sure -- I think I understand how this concept would work if prices are going down, but maybe as you go -- if you're going to have an -- let's say you have a cap, you can't go more than 10 percent above something, and the question is: What is that something? When is it measured? That's all. You can

think that through.

DR. CROSSON: Amy, did you have a comment on Bill?

MS. BRICKER: Yeah. So I think they're proposing, Bill, CPI, which is, you know, no more than -- it looks like 2.6 in the last few years.

[Comment off microphone.]

MS. BRICKER: Now it's 0.9. So that might get to it. But I didn't raise this earlier, but I just -- in the commercial space, you don't see pharmaceutical manufacturers agreeing to something this aggressive. So they will come to the table with respect to inflation protection, but nothing to this extent. And so I do worry about what we look for, agreement from the industry, and we need to do something that's -- I don't know what's reasonable, but I think -- I concur that if it's something like 10 percent, you will absolutely see everyone going to 9.9 percent.

The only other thing that I wanted to comment, when you had mentioned the clawback, how you might then true up with the beneficiary, because their out-of-pocket was based on something -- right, so we have to chase them

and adjust their out-of-pocket. But something to consider.

DR. CROSSON: Okay. Kathy?

MS. BUTO: I think Kim --

DR. CROSSON: I'm sorry. You wanted to say something, Kim?

MS. NEUMAN: We just wanted to make one clarification about the ASP inflation limit option. So as we wrote it up, it was based on the Medicaid approach, which is to take a base year and then to measure inflation with CPI-U relative to that base year. It wouldn't be a year-by-year like 10 percent or 2 percent or whatever. It's a cumulative percent change from a base year, and so that moderates the sort of fluctuations that can happen over time.

DR. CROSSON: Okay. Thank you for that clarification.

MS. BUTO: So I strongly support the recommended ASP add-on hybrid approach that you all came up with. The WAC plus some percentage below 6, I don't think we ought to just make it up, I guess is my feeling. We ought to have some feeling of reasonableness, whatever that might be. And ASP data reporting I think should be required.

So my comments really go to consolidated billing and the ASP inflation limit, and let me just say I like the concept of weighted average pricing if it applies to an episode bundle, so if it's bigger than just the drug, because then there's the ability of the provider to trade off other inputs for the right treatment for that individual, yet the overall payment is capped. So I like that idea. I'm very queasy about it applied to "therapeutically equivalent drugs" because it's hard to identify what those are. Some of them are going to be off-label versus label. The experience so far has been whenever CMS has done something like this, LCA, least costly alternative, functional equivalence, Congress has come along and limited their authority to proceed. So it's got a little bit of a history there.

I agree with Jack that I think if a case can be made for a drug-to-drug consolidated coding, it would be for biosimilars and the reference product. To me that's a decision or a judgment made by the FDA. It's a different body, scientifically based body, and so I think that's one where, again, I think there's -- other people have mentioned this. That's sort of the cleanest, I think,

category. I'm nervous about expanding it further for a variety of reasons.

I also think -- and I've said this before -- that a payment below the cost of a drug, even a drug that's needed for an individual patient, is going to drive practice. And I don't like the idea of physicians being driven by their own financial liability to cover the cost of somebody's treatment to prescribe something. So that's just something that I would mention.

I think it will affect research in a category, and I happen to think that incremental innovation has been important in the treatment of certain conditions like childhood leukemia, for example.

So that's on consolidated billing codes. I like the concept, but in the context of an episode, and then if we were doing it with a drug category, I think the cleanest one is the biosimilar and reference product.

For the ASP limit -- and I sort of alluded to this in my clarifying comments -- I really prefer for Medicare to set a payment limit. I think the concept is the right one. Price increases, that there ought to be some limit associated with inflation. I think what will

happen is high launch prices, as you've pointed out, and I also think, knowing from experience, manufacturers will limit their price increases to below whatever that limit is.

Do I think setting a payment limit is going to put the physician in a bad position? No. But I think we've seen the experience of the sequestration where what happened when the ASP was dropped was manufacturers negotiated a limit that would allow them to continue to do business with a physician. So I think it has the same impact on the manufacturer. I think it's a lot simpler for the beneficiary to know and to pay, and maybe it's just as simple to do it the rebate way. I don't think so, but, anyway, I actually think at a bare minimum I would really like us to lay both options out and not just choose the rebate option, and mention in passing the other option, which I think is more desirable from both the beneficiary and administrative perspective.

DR. CROSSON: Thank you.

MR. PYENSON: Thank you very much. I support all the options. Just a few comments on them.

On the consolidating billing, I believe the

biosimilars but other categories, hyaluronic acid and things like that, come to mind where there's multiple J codes that seem to be very similar, could be subject to that. And I'm wondering if there could be illustrations of different hypothetical consolidated billing codes, if that's something that could be done for illustration.

On the ASP inflation limit, I know the inflation limit everyone thinks about is CPI, the Consumer Price Index. These products do not resemble, in my mind, consumer products. They are not bought by the consumer and you have a doctor putting them in your veins. So I think there's probably other price indexes that might be appropriate, more appropriate, such as Producer Price Index or Wholesale Price Index. And some of those have different characters. So I'd ask for an exploration of potential alternative indices there.

I agree with Craig on the ASP add-on. Of the options, I prefer the hybrid. But if there's interest, I would suggest we could probably add perhaps three CPT codes or have add-ons to current infusion where there were categories of extra payment that corresponded to the extra work or extra practice expense for broad categories, and

consider those as perhaps a cleaner approach than a percentage add-on.

And, finally --

DR. MILLER: Bruce, would you do that again?

DR. CROSSON: The last point.

DR. MILLER: Run those last two sentences.

MR. PYENSON: As opposed to a percentage add-on, have a -- for different types of drugs, have a modifier or a CPT code that corresponded to the extra practice expense or supervision expense for that type of drug.

MS. BUTO: For physician payment [off microphone].

MR. PYENSON: For physician payment.

DR. MILLER: For the physician payment. I kind of followed that, and I have a little experience, all of the scarring, in that area. But are you saying that and then in that instance the ASP would not have an add-on?

MR. PYENSON: Yes.

DR. MILLER: Okay. That's what I wanted to catch.

DR. CROSSON: And that would be in addition to the administration fees that the practice is already

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getting.
MR. PYENSON: Right. It might be a modifier on those administration fees.
DR. CROSSON: Thank you
MR. PYENSON: You're welcome.
And, finally, on the ASP data reporting, which I support, there's another part of the food chain that might be important, which is the distributor and wholesaler. So something collecting data, something like what NADAC does, the National Average Drug Acquisition Cost, might be a useful part of the story since physicians and others don't buy directly from the manufacturer, they buy often from a distributor. So if there's interest in that, if we think that's useful.
DR. CROSSON: Okay. Thank you very much, Jack.
DR. HOADLEY: Just a quick follow-up, if I may, on the -- I've been thinking about Amy's original point on the consolidated codes, and I think one point I think somebody else picked up, which is that -- because I clearly -- we clearly don't want to reduce the incentives for biosimilars to come on the market. I mean, I think that's an important point. But I do think -- and somebody else, I

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think, made this -- that the averaging between the original and the biosimilar would actually put to the benefit of the biosimilar.
But there's one other thing we could throw in the mix, and not so much as a recommendation, because it's sort of outside of Medicare, but at least to talk about in the next, which is, as was noted somewhere -- maybe it's in the other paper -- unlike, for other drugs, there's no initial exclusivity for the first biosimilar that comes onto the market, which gets us in the small-molecule drugs, the first generic gets a six-month exclusivity, which creates an incentive for them to come in. And we could at least mention that such things are possibilities in this world.
And the only other thing I would mention is that, you know, with a lot of the stuff on oncology, I mean, we've had other discussions about ways to think about oncology bundling, and I know we'll, at some point, come back to those. But, you know, this might not be the end of the story for sort of dealing with some of the issues around the oncology drugs.
DR. CROSSON: Do you want to comment on that?
MS. BRICKER: I do. So I just want to be clear.

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I am absolutely in support of consolidated billing codes for biologics and biosimilars when there is a market, and maybe, Jack, to your point, we could, you know, not consolidate the billing code until there is more than one product in competition.
My fear -- and maybe I wasn't as articulate as I could have been originally -- is that the manufacturers of the products that are biosimilars are, in fact, the same as the innovator product, and you will never see 100 percent conversation from innovator to biosimilar. And what you would be doing, by consolidating the billing code, yes, you would be paying -- you would be incenting the biosimilar -- I agree with that and the economics around that -- but you would be absolutely destroying the innovator product's ability to stay at all viable, and, in turn, the manufacturer of that innovator product, I don't know that they would see a pathway to continuing to put biosimilars in the market if that's immediately the reaction of the market.
And so that's my concern. Whether or not it's founded in evidence, we don't -- this is unique, right? So it's just based on, you know, conversations I've had with

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those in the market. That's the concern raised. And so I thought it prudent to share with the Commission.
DR. REDBERG: That depends on, then, that assumption that the biosimilar is coming from the same company that made the innovator product. If that changed, would your --
MS. BRICKER: So not necessarily innovator in that exactly biosimilar, but that innovator is making a biosimilar for something else, not the innovator product but a different -- you know what I'm saying? -- not necessarily the authorized generic or the AG of the innovator, but they're in the business of making biologics and so maybe they're going to make a biosimilar of someone else's innovator product. And so that's what I'm concerned about.
DR. HOADLEY: I mean, I think it's certainly reasonable to think about whether there could be a lag period of some sort, or think about, you know, does this require three in the market versus two. But part of the response we'd be looking for, I think, is for the originator manufacturer -- the original innovator to be bringing its price down, potentially.

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I mean, that would be a -- one of the potential responses to this kind of bidding, and then they -- that would allow them to stay in the market. They've had their 10 years or whatever to be exclusive. They ought to be able to bring the price down at that point, you know, under competition. We don't see that in the small-pill market but you basically just see nobody buys the brand version anymore but it's often still on the market at something close to its original price, which has always been a little puzzling to me.

MS. BUTO: I think -- I mean, I'm really -- I'm struck by Amy's point, because I think it was similar -- I was trying to make a similar point with -- it's the general issue of discouraging a market from continuing to develop, and I think it's important for us just to keep that in mind, and which is why, I think, in the last go-around in June, I feel really strongly we ought to be clear that whenever they get into this territory they need to think about those unintended consequences of discouraging other manufacturers from even jumping into a category, because they already see that it's going to be grouped together.

So I just think that that's not something to be

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easily dismissed. We ought to make sure that it's in the criteria when CMS looks at something like this.

DR. CROSSON: Okay. Thank you. That was a good round of 2.1. Now we're going to move on to Round 2.2.

Let's see. Could we have Slide 12 up please?

So this is the proposed policy option for the restructured CAP. On the previous slide, for those of you who are working off paper, we also had, you know, the dichotomy options, for the most part, for each of these two, but these are the recommended ones.

So I think what I'd like to do is have a discussion about the general level of support, or lack thereof, for this idea, but also, do people agree with these six bullet points, or would you prefer something else -- for example, mandatory rather than voluntary focus on a subset versus all drugs? Multiple regional CAP? I mean, you can imagine the variety of options there -- so that we and the staff, you know, can begin to hone the model or set of options within the model that people can support the best.

So let me see hands for comments here.

Okay, I think I'm going to start in the direction

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-- the only direction I haven't done so far today, which is to start here and go that way. Okay. Starting with Craig.

DR. SAMITT: So as I mentioned earlier, I'm fully supportive of exploring the CAP model, and I don't mean to dodge your question about each of the sub-elements here, but we referenced earlier the fact that this program was unsuccessful in the past and I think it would be helpful to understand, of these sub-elements, were any of them -- did any of them particular make the prior model unsuccessful?

So, for example, the voluntary piece, I would imagine that making the program voluntary is -- may very well be problematic and perhaps that's why there wasn't sufficient penetration the last time around. And the same may be true of some of these other elements. So I think it would be useful to know which of these may have influenced poor success in the past.

The other thing I didn't mention earlier, that I would strongly advocate for in the CAP model, is a means of holding the prescribing clinicians harmless, that we're not talking about elimination of revenues that they may have very well become reliant upon through the ASP+6. So have we evaluated that to determine how do we implement a CAP

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model which would neutralize any plus payment and yet this may very well be baked within the operating requirements of many of these practices or hospitals. So I'd like to understand that a little bit more, just to make sure that that hold-harmless methodology, whether it's the codes that Bruce described or what have you, would be a way to assure that there was a revenue stream to the prescribing clinicians but not any kind of perverse incentive, one way or the other, in terms of what is actually prescribed.

DR. CROSSON: So let me just comment on that, and I'm going to ask Kim, also, to make sure I get it right.

So, yes, I mean, entirely here the notion is to provide, through a shared saving arrangement, a revenue flow to physician practices based upon the physician practice undertaking to manage the cost of Part B drugs. One would imagine, or hope, that for practices that are successful in doing this it would be at least as remunerative, if you want to say, as the current model, and for practices who can't do this or won't do it, it would be less. And that's the whole point about it.

In terms of the -- of why the other model failed, there were a number of reasons, but as I remember -- I

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think we talked about this at a previous meeting -- is that RTI, who did an analysis of it -- and this is my memory -- was that in their commentary they said the absence of the ability to have a formulary, which kind of neutralized negotiating strength for the CAP, was one. And then the -- I'm sorry -- what's the term for the -- not the stock replacement model but the model that was used by the physicians had to order the drug every time the patient needed it, that the administrative burden created by that, those were the two things that, most importantly, those were the two things -- most important things that sunk it. Is that --

DR. REDBERG: That was GPO.

DR. CROSSON: No, no, no, no. Kim, can you help with this?

MS. NEUMAN: Yes. I don't know if there was ever a term for it, but the way it worked is that the physician was supposed to submit an order to the CAP vendor for an individual patient before that patient's visit, and that -- the logistics of that were bothersome.

DR. CROSSON: To say the least.

DR. COOMBS: And the patients would show up for

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their designated time to receive a chemotherapy and they wouldn't have --

DR. CROSSON: Right. So that is not the option we're talking about, as a stock replacement model, or the GPO model, just to be clear.

Do you want to spend just a second describing the stock replacement model and the GPO model?

MS. NEUMAN: Sure. So in a stock replacement model, what would happen is the physician would place -- or the hospital would place an order for the drugs that they thought they would need for their Medicare patients over some time period, and then they would have them onsite to use as patients came in. And then if they didn't have a drug that they needed, they could use it from their own stock and then the vendor also would replace that. So there would be those two ways to get the drug to the patient.

Under a GPO model, the idea is that a GPO would negotiate prices on behalf of Medicare, and the physicians and providers would get the drugs through their normal process, through distributors and wholesalers, and then there would be a process where Medicare would pay the

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physician that negotiated rate, and the physician would be trued-up, so that they didn't have any gain or loss. They would be paid exactly the amount that the government had negotiated the price to be.

DR. CROSSON: Right, and I would presume, although we're getting down into a level of detail we haven't worked through yet, that in addition to that there could be a shared savings incentive based upon the pattern of practice. Correct?

DR. SAMITT: And that was the piece that I was most interested in, is it was just purely a neutral payment -- no risk, no gain, no loss -- that isn't equal to the opportunity that exists today for providers.

DR. CROSSON: That's not the intention.

DR. SAMITT: Right.

DR. MILLER: And I wanted to also just say, I would have said exactly the same thing -- the formulary and the hassle for the physician's office really were the two things. But the thing I would also ask you to keep in mind, as you think about this, sort of the first point. To the extent this happens in the context of the regular buy-and-bill framework or system that's there, you know, a

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physician's incentive is going to always be balancing that off. So you can think of voluntary or mandatory but you can also think about what you do on the buy-and-bill side to incent people to move, because -- and when this came along, physicians, I just don't think saw a lot of value in stepping out of the buy-and-bill situation.

And then I want to clarify -- and I may be out of a job right after this comment. When he said -- you used the word "hold harmless," and then you sort of agreed. What were you thinking was being held harmless?

DR. CROSSON: Okay. So I can't remember. So what comment was that?

DR. MILLER: We'll start with him. You said -- what did you think you were -- what was being held harmless?

DR. SAMITT: So I guess when we look at the net remuneration to clinicians, given ASP+6, versus the cost of drug acquisition, what is the net effect to the practices? Is it neutralized? Sometimes there's a loss. Sometimes there's a gain, based upon negotiated rates. Or is there, on average, a net gain?

And so if -- you know, I don't remember what the

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statistics -- that 75 percent of the drugs are ASP+2, right, or higher.

MS. NEUMAN: It was for two-thirds of the drugs we looked at, 75 percent of the volume was at 102 percent of ASP or less.

DR. SAMITT: Right. So there's less likely to be a loss, on average, to the clinicians in the dynamics of ASP+6, so that would result in generally a gain to the clinicians as a result of this program. If we put in place a CAP model where there's zero loss, zero gain, then we're going backwards in terms of clinician reimbursement. And I may not be understanding this correctly but that's what I mean by hold harmless, that what is the financial impact of this, on average, to clinicians versus the ASP+6 model.

DR. CROSSON: Okay. So let me clarify what I was saying in response to what you were saying. I wasn't saying that I thought this program should hold the physician average revenue at ASP+6. It's hard. We've also got on the table other options to reduce that. What I was saying, though, was that the intention here is to build in -- you know, similar to our efforts with delivery system and payment reform -- incentives for the physicians to

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participate in the management of drug costs, and that we would construct a -- hopefully -- we would construct a model that would provide for physicians who are willing and successful at doing that, to provide, you know, something that would at least cover costs and potentially provide additional revenue, based upon the success in sharing overall savings, money for the Medicare program and money for the beneficiaries.

So that was what I was responding to. It may not be exactly what you were referring to.

Alice on this?

DR. COOMBS: Yes. So I had to check with Jack, but with that 102 percent -- because it sounds like, you know, we're getting down to something that's really, really slim -- we haven't taken into consideration how many of the oncology practices are hospital-associated, and of those hospital-associated practices, how much of that hospital-associated practice is participating in 340B programs, with great discounts off of the oncology drugs. So that it's a really complex picture when you look at it.

You know, I was just thinking about this. This is not simple. It just -- I think some of the things that

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we're trying to decide here become very convoluted when you talk about a hospital-based oncology practice versus an oncologist in the trenches, doing, you know, everything by themselves.

DR. CROSSON: Okay. So, Paul, on this point?

DR. GINSBURG: I'm a little confused about whether -- it sounds like the CAP is going to be a hybrid of a company which does what Part D plans do, as far as establishing a formulary and negotiating prices, but also a distribution company, to be physically distributing the drugs to physician offices?

DR. CROSSON: It could -- depending on whether we choose the stock replacement model or the GPO model, that would be true or not.

DR. GINSBURG: Oh, I see. Yeah, because I think that would be very hard to do, to have one company do both, and I think the big opportunity here is really on the formulary.

DR. CROSSON: Yes. I agree. So let me just -- where -- we were going down this way. We had Craig. Now we've got Bill Gradison and then Kathy and then Bruce.

MR. GRADISON: I'm trying to sort out what this

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would add if all of our other recommendations were implemented. I think I understand it but I'm not so sure that it would be worth the complications, not just for the practice but for all the different elements here of moving to this system.

I appreciate the desirability of having incentives for physicians to be efficient. There are very direct incentives in MA and in ACOs for them to make wise economic choices in their selection of drugs -- at least I think there are. Well, maybe not. But I just -- so long as it's voluntary, that's -- I'm not going to object. If it were mandatory I'd have a lot of problems with this thing.

DR. CROSSON: So, Bill, I'll just -- I mean, we were talking at the beginning about, you know, a set of recommendations. So one crude way of looking at this is that we have on the table a set of administrative solutions, and we have at least one, that is the CAP, which has some characteristics of a market-based solution. And so while it's complex, which I agree with, so is the way that Part D was put together, right, with the creation of new entities, the Part D plans that needed to be stood up

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and managed. This may or may not be the same level of complexity. It could turn out to be more or less. But the notion here is that, you know, arguably, there is a place for a kind of a market-based solution to the issues.

Kathy.

MS. BUTO: Yeah. I'm sort of, I guess, the mirror image of Bill on this one because I don't think it's going to work unless there is some element of mandatory in it, that as long as it's voluntary, I think back to Craig's point. I'm not sure why physicians would necessarily want to give up ASP plus whatever the add-on is, because that's so sure and attractive and it creates that additional revenue for physicians.

So I think this is -- this can be most successful if there is a way to think about it as a replacement for the current buy-and-bill system. How you get there I don't know. I think that's really definitely the hard part. It may be in small increments. It may be that ASP becomes so -- the add-on is so low that pretty soon physicians really can't buy-and-bill, and have that be a viable approach.

So I think we have to think about this a little bit more like a, what element of it could be introduced as

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mandatory for at least some subset of drugs or, you know, some area of great concern, because I think as long as it's left voluntary it will not work.

DR. CROSSON: Bruce.

MR. PYENSON: I did a quick calculation based on the numbers in the presentation. I think we're talking about something like $40 per member per month or $40 per beneficiary per month. Does that sound right? For the scope of Part B drugs, roughly --

DR. MILLER: 22 billion on a 600 billion base something like that.

MR. PYENSON: Something like that, yeah.

So this is probably not enough for a Part D plan, right, or a Medicare Advantage plan, where a total budget of -- I don't know -- $800, 6-, $8,000 PMPM, depending on where you are.

I say that because what we're creating -- to Paul's point, an intermediary, we're creating an opportunity for new enterprises like Part D. So it's an intermediary that is going to need its own profit and maybe justifies its services maybe through bringing efficiency or not.

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So, given the relatively low dollars, the $40 PMPM or so, I think, to Kathy's point, this would need to be a mandatory program if it were going to work.

So the question, the concern, or puzzle I have is how does this intermediary account for itself. So, if it's truly handling something like $40 per member per month and if it's handling that on the basis of being a third-party administrator, then a reasonable profit for that is some portion of its administrative expense. If it's handling its intermediary role as though it has possession of the product, then it's a much, much bigger profit, and that raises questions about the viability of the enterprise, financially.

DR. MILLER: And so just to walk my way into your comment, $22 billion in Part B spend off of 550-, $600 billion base, you get about 4 percent, 4 percent of per capita spend. You're ending up with about 400 bucks and dividing that by 12 months, somewhere in there, and then that dollar amount, that's the implication of whether this -- I can't remember the phrase you used, whether it carries itself.

MR. PYENSON: Sustainable, perhaps.

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DR. MILLER: Yeah, there you go. Okay.

DR. CROSSON: Bruce, are you done?

MR. PYENSON: I'm done.

DR. CROSSON: Yeah. Okay.

MR. PYENSON: So I'm neither supportive nor not, but there's lots of implications here that from establishing this as a new type of business in American health care.

DR. CROSSON: Right. So, I mean, one question -- and I don't want to get in too far into this, but I said new entities, and that could be the situation. But it also could be that existing entities, who are now present in the marketplace performing somewhat similar functionality, could in fact absorb this as a business, which would arguably require less up-front cost perhaps.

MR. PYENSON: Well, that was the case with Part D plans, Humana and Aetna and so forth.

DR. CROSSON: Right.

MR. PYENSON: In this case, I think probably McKesson or maybe the PBMs could step into this.

DR. CROSSON: Okay. On this point?

DR. DeBUSK: I was going to point out, I like the

way Bruce was looking at this, benchmarking the cost of this new intermediary based on a Part D plan. I would benchmark it, but I think I would probably use more of a GPO-type model, which I think you'll come up with a much lower per-member per-month threshold because, to Jay's earlier point, they operate in an entirely different cost point.

DR. CROSSON: Now, do we have Amy and Pat on this point? Amy?

DR. BAICKER: I have another comment.

DR. CROSSON: Another comment.

Pat?

MS. WANG: So it would be a very big new concept, and to Bruce's point, one of the things that I think could expand the sort of -- the size of the enterprise is if I'm a doc that is Medicare and I'm purchasing through a CAP for my fee-for-service patients, I don't see any reason why I wouldn't extend that activity to my Medicare Advantage patients, which could have sort of a salutary effect on benchmarks over time.

I don't know whether -- if this thing really worked, I think that that's a big if because it doesn't

exist, but if it really worked, is there a reason that it couldn't be available for commercial patients and others? Because if you're an oncologist and you've got a mixture of patients, a payer mix in your practice, I would think that they prefer to purchase from one distribution channel and not three or what have you. So that's a question.

In terms of the voluntary versus mandatory, I have to say mandatory -- I don't know. It sounds like a big -- mandatory is not a concept that I think is easy to swallow, even for me just sitting here, because the thing doesn't even exist. So that's a big mandate.

But maybe something that should be considered is in sort of shaping what a CAP, a voluntary cap could look like is -- we just went through a whole series of sort of fee-for-service, inflation caps, and ASP+ changes. If one believes that a CAP could purchase at or below the level of the inflation capped Part B approach that we just discussed, perhaps giving an incentive to physicians by saying purchase through the CAP and it's +6 would get a lot of voluntary uptake, without having to tell people, you must do -- I mean, I think that would be big.

I understand the need for large numbers, but

maybe we should think of ways to encourage a way to get that large number in a voluntary fashion through incentives.

DR. CROSSON: Yes. And on your second point about potentially the addition of commercial -- together with Medicare, that brings up an issue we haven't brought up, which is a potential downside of the model for providers, which is the notion of acquiring and billing for drugs in two different ways. And if, in fact, the model proved to be successful in Medicare, I see no reason why it could not be expanded, and that could potentially be a way of resolving that design problem as well.

Okay. So how are we going? We're going this way. Amy is next.

DR. BAICKER: I'm supportive of a voluntary program. I think the way that you would get participation is by taking the action more aggressively on the fee-for-service side, so less carrot, more stick.

I think you've got to allow the entity, and again, we don't have to re-create this wheel. You can leverage PBMs from a UM and a formulary perspective. They can also incorporate inflation protection and do all that

negotiation on behalf of the program. And I would support a GPO.

So this exists today in 340B. You call your wholesaler and you say, "I'm placing an order on my 340B contract versus my acute care contract," and this is very simple. It really isn't that difficult. It's just letting the wholesaler know which contract you're purchasing off of, and you do that in retrospect. Yes, there has to be a true-up and an audit and all those things. The infrastructure has to exist, but you can model it simply after what is done today in 340B.

I don't think you have to expand it necessarily to the commercial market. The commercial market today has these levers, not through drug acquisition, but all the other levers are available and are used widely in the commercial market. So we can look to that space to see what maybe best practices are.

There's great success that the TRICARE benefit has had in acquiring and -- drug through VA contract. I know that's not what we're talking about here, but the reason they're successful is because about 60 percent of the top 200 drugs are what they are purchasing. They are

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not purchasing every single drug that's made, and so they have some ability to allow, again, those simple marketplace levers to work.

I'm not saying or suggesting that VA contract be in place, but that's just another example of the government allowing -- if you take the handcuffs off the program and you're actually able to select certain drugs by which you would negotiate better pricing with manufacturers, I think there is tremendous savings here to be realized.

DR. CROSSON: Thank you.

Coming up this way, Jack and then Brian.

DR. HOADLEY: So I guess my position on this is skepticism more than opposition, although I would tilt to thinking this has a lot of problems. Again, I guess it's my skepticism that makes me less enthusiastic about it is a better way to put it.

And a lot of the points have been made. I guess a couple of things that I thought of among the options are certain of the things -- I mean, first of all, I actually kind of like the set of options you put out here, but then I started thinking about how some of them intersect with each other. So if one of the incentives in a voluntary but

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encouraged participation is that we'd be eliminating buy and bill or really getting away from buy and bill and then we say a subset of the drugs, that means the doctor is going to be -- or the hospital or the clinic is going to be ordering some drugs through the CAP, but still having to maintain a buy and bill operation for the drugs that aren't included. And there's a lot of logic to this subset, but then it sort of means you don't go as far, and you get two sets of systems going.

There are a lot of reasons -- and Amy just articulated some of them -- for a formulary, but also similar to our discussion on some of the consolidated billing, within this set of drugs that we're talking about on the Part B side, I am trying to think through how many of them would be sort of conducive to multiple choices that are broadly accepted as options by clinicians. So maybe that's true in some categories of drugs, where you can say, "Okay. There's Drug A, B, and C, and if only one of them is available through the vendor on the formulary, that will be fine." That's certainly not likely to be the case for oncology, where I think generally oncologists look at that whole array of options. And there are relatively few drugs

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that are straight substitutes.

So I find some issues in how the formulary would sort of play out and whether that goes back to the acceptance. So, if I go with this option, if I'm the oncologist or I'm the rheumatologist going with this option, I say, "Well, yeah, except now I'm constrained by their decision of a formulary," which has this today and could change tomorrow. That's going to be something that's going to maybe make me say, "No, I don't want to participate." And I think you think back to the experience a decade ago, and yes. So we can fix the delivery. The stock replacement model would be a big fix over the per-patient kind of ordering system, but I just wonder if in the end, there would be enough concerns about some of the ways these other pieces would operate to end up in a situation where not a lot of clinicians would agree to participate, including the multiple vendors, which, again, I can see the advantages of. But it's going to make a choice.

So it's just like the consumer trying to pick between plans, and I have three drugs, and one of them is on the formulary for Plan A. Another one is on the

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formulary for Plan B, but I've got to pick one plan. So the doctor is looking, "The drug I like to use for this condition us on Vendor A's list, but the drug I use for that condition is -- so now do I set up a relationship with two different vendors? And I'm worried about a lot of the complexity.

So I'm open to continuing to work through how to make some of those things work, but I remain skeptical that we'll end up with something that in any kind of a reasonable time frame we can make work.

DR. CROSSON: So just a couple of thoughts on that concern, the primary concern, which I think is a real one, and just a couple thoughts about how that might be mitigated, and drawing from the experience of the narrow network-based MA plans, for example, or the integrated practice MA plans, where the same situation exists, where the physician organization is, in fact, helping to create the formulary but then has to live with it. And the two elements would be, number one, the level of involvement of the physicians in the determination of what's on the formulary, and the better, the higher, the more intense the better, although that is sometimes difficult to arrange

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where the physicians are not part of one entity. I know that.

And the second one would be managing an exception process. So, at least in the settings that I'm describing, no formulary is absolute. There is always a patient -- not always, but many times, there's a patient or a few patients who, for valid reasons, need the other drug that doesn't happen to be on the formulary. So, in that model, the determination to include a drug or not on the formulary is not absolute. It's essentially what the physicians are guided to, and then there's usually some process that in the event that a patient needs a different drug and that's justified, then the availability of that other drug can be made possible. So there are ways to mitigate the problems.

DR. HOADLEY: Jay, can I just add one thought to that?

DR. CROSSON: Yeah.

DR. HOADLEY: In prior iterations of this discussion, we had also talked about clinical pathways, and given the nature of the drugs and the Part B class, you wonder whether operating pathways versus operating formularies may actually be a better solution here, because

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it would offer that degree of flexibility and would probably also tie even to the notion of the shared savings opportunities for sort of payment for prescribing on pathway versus off pathway. So that may be another consideration that could be folded into the cap.

DR. CROSSON: I agree with that. It's very similar to the idea. I mean, where in one case, you get, let's say, a bunch of oncologists together and they say how should we be dealing with small cell cancer of the lung, and they kind of agree that for most patients, these drugs are the ones that we would want to have available, or in this model, here is the recommended pathway for dealing with patients that have this. They both include the notion of the most likely and recommended pharmaceuticals.

But then there's always the need and the option for off-guideline, off-pathway, or off-formulary provision of medications.

MS. BUTO: Jay --

DR. HOADLEY: I think those are --

MS. BUTO: -- a follow-on question to Craig's.

DR. CROSSON: Yeah, Kathy.

MS. BUTO: Is pathway the same thing as using

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tools like step therapy in accordance with guidelines, or what is pathway in your definition? I'm just curious.

DR. SAMITT: It wouldn't be equivalent necessarily to a step therapy. It would more be that there's a universe of options -- oncology, chemotherapy treatment is probably a really good example. That there are a variety of different combinations and alternatives, but their specialties would designate which combination or which agents would be preferable. And it wouldn't be viewed as a step. That you have to go through A before you go through B, but that the evidence would suggest that this would be the choice that you should --

MS. BUTO: Okay. So I just think it would be helpful to mention not just that idea, but some of the other tools that we may not want to actually recommend but should look at, things like step therapy, instead of a formulary, which would be an up or down decision or a black and white, as well as I wouldn't say increase coinsurance, but maybe reduction in coinsurance for some drugs that beneficiaries might -- and doctors might want to recommend.

So I think we ought to look at a combination of different potential tools that could be at least mentioned

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like that.

DR. CROSSON: Jack.

DR. HOADLEY: Just following on your comment, I mean, I think what you describe inside an integrated system has worked very well. It's worked very well within the VA system, at least I would argue it's worked very well.

I think the question is how does that translate to a broad array of clinicians across a community, and I think, to some ways, the oncology issue seems to be a bit different from some of the other categories and may say we might get more bang for the buck to go back to some of those options we've talked about before about different ways to address bundling or other kinds of things within the oncology world. Maybe there are ways within some of the other specialties. I mean, again, maybe thinking of these things more sort of like specialty, because the set of drugs we're talking about is for a fairly narrow range of health conditions, at least today, so yeah. There are rheumatoid arthritis situations. There are multiple sclerosis -- you know, there are other things where these Part B drugs come up.

And thinking about how that fits into these kinds

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of models maybe worth thinking -- I just think it's something that's going to take a lot more thinking through to get something that feels like it will end up workable, but it's good for us to begin the thinking. It may be the kind of thing where we could have a good discussion. We had some of this in a previous chapter, but have a good discussion of why this option has potential strengths, has some other potential limitations, and maybe it's one where we'll stop short of a recommendation.

DR. CROSSON: Brian.

DR. DeBUSK: Well, I'm very supportive of the CAP idea, and I'd like to get back to Slide 12 and at least weigh in on some of the questions that are posed on that slide.

We've talked about this before, but I see the CAP as an umbrella for the options that we've previous discussed, things like the ASP limit, things like restructuring the add-on payment. But to me, a CAP is just a nexus of contracts. I mean, it would look like a blend between a group purchasing organization and a Part D plan, and I think it's important to know that to allow whatever this CAP plan is, to not only maintain a formulary, but

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also have a shared savings program.

And I would separate the physical distribution from basically the contracts. So, if a distributor wanted to be a CAP provider, I don't think we would stop them, but I don't think that would be necessary, which gets into this whole idea of a replacement model.

You know, we've talked about the stock replacement versus the GPO model. I would propose the business-as-usual model, which sounds a lot like the GPO model, where physicians or hospitals could subscribe to the CAP plan of their choice. The physician or the hospital would order -- much like Amy mentioned -- would order from their wholesale distributor, as they always do, and they would file claims.

But I think, much like a GPO, this CAP plan could process the claim. They could calculate the rebate. They can enforce the inflation limit for us and manage the shared savings program, and I think what you would have is a third party that while they're not technically mandatory, I think we could use differential payment. SO, for example, if we were to reimburse at, say, ASP+3 percent and then let you get the other 3 percent back from your CAP

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plan, then it would be incumbent on the hospital or the physician to choose the CAP plan that best met their needs.

And I think the other issue was raised about multiple CAP vendors. I want to point out over 60 percent of hospitals use more than one GPO already. So the idea of having to say, "Well, I'm on this CAP plan or that CAP plan," I mean, hospitals do that every day, all day.

Thank you.

DR. CROSSON: Okay. Thank you, and thanks for a good discussion, not just on this CAP issue, but on all of them. My sense is that I haven't seen any of the members of the presenting team racing for the door either to quit or to start working right away, although I think both of those options still exist. And we look forward to a honed presentation in January. Thank you.

[Pause.]

DR. MILLER: Is this the second appearance of Sydney in one day? Man, she's bringing it.

DR. CROSSON: Yes, indeed. Okay. So now we're going to take up again the issue of behavioral health and have a couple of ideas to bring forward. So, yes, we have Dana, Kate -- and, Sydney, are you a twin, or is this you?

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Okay. Who's going to start? Dana.

MS. KELLEY: Good afternoon. Today Kate, Sydney, and I will provide some background information about behavioral health and why it is such an important issue for the Medicare program, but also why it is a difficult issue for Medicare to tackle. Then we will discuss two policy areas related to behavioral health that the Commission may want to explore.

At some point in their lives, many people have mental health or substance use problems that may require treatment. Estimates differ on the prevalence of behavioral health disorders, depending on the population studied and on how the disorders are defined and identified. The National Academy of Medicine recently reviewed research on this topic and concluded that between 14 and 20 percent of the overall elderly population has a mental health or substance use disorder.

An even higher share -- 30 percent -- of all beneficiaries self-report a behavioral health disorder. The discrepancy partly reflects the fact that beneficiaries who are under 65 are much more likely than elderly beneficiaries to have behavioral health disorders.

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Beneficiaries who are under 65 are four times more likely to have schizophrenia and over two times more likely to have major depression or other mood disorders.

It is clear that people with behavioral health disorders have higher mortality rates. Studies have found that people with these disorders die an average of 8 to 30 years earlier than others. Although rates of accidents and suicide are higher in people with behavioral health disorders, the leading causes of death for this population are similar to what we see in other adult populations -- heart disease and cancer.

That's because behavioral health disorders tend to exacerbate existing physical health problems and contribute to the development of new ones. In part, this is due to lifestyle factors. People with mental health disorders are two times more likely to smoke. They also are more likely to be sedentary and to have poor diets, and they frequently have co-occurring substance use disorders.

At the same time, treatments for behavioral health disorders can themselves worsen physical health. For example, antipsychotic medications are known to cause weight gain, obesity, hyperglycemia, and Type 2 diabetes.

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Also, the presence of a behavioral health disorder can make it more difficult for patients to adhere to treatment, which can complicate care for physical conditions.

Overall, the combination of behavioral and physical health conditions in any patient can be problematic, resulting in increased symptoms, greater functional impairment, and decreased length and quality of life.

As a result, behavioral health disorders are very costly conditions for beneficiaries and for the Medicare program. Per capita Medicare spending in 2013 was about two times higher than average for beneficiaries with these disorders.

It's important to note that the aging process may increase vulnerability to behavioral health disorders. Depression and anxiety can be caused or exacerbated by chronic illness, loss of motor and cognitive function, pain, and grief -- all of which are common in the elderly.

In addition, just as some treatments for behavioral health disorders can worsen physical health, drugs prescribed for common physical conditions in the

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elderly can cause or exacerbate behavioral health issues.

And age-related changes in the metabolism of alcohol and drugs, including prescription drugs, can cause or exacerbate substance use disorders and can increase risk of side effects and overdose.

The health care system is widely perceived to be deficient in: identifying and treating new behavioral health disorders; managing the care of patients with ongoing or serious disorders; and addressing crises when they occur.

The problems are numerous and systemwide. I've outlined some of the problems here and on the next few slides, and I'll touch on just a few.

One problem is that our behavioral health delivery system may have been shaped more by financing than by best care practices. Experts often cite the Medicaid Institute for Mental Disease, or IMD, exclusion as a prime example. The IMD exclusion prohibits federal Medicaid funding for inpatient care for patients aged 21 to 64 in freestanding psychiatric hospitals, including government-owned ones. This prohibition likely contributed to the deinstitutionalization movement that downsized and closed

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many state and county psychiatric hospitals between 1965 and 1985.

Today most experts agree that there is an acute shortage of government psychiatric hospitals, which historically have cared for patients who are the most difficult to treat. Lack of capacity to serve these most seriously mentally ill patients has placed substantial burden on both the health care system and the criminal justice system.

System-wide problems also include a shortage of mental health and substance use treatment professionals. Experts also cite an overall low rate of evidence-based medicine in this area. In addition, integration between physical health care and behavioral health care is poor.

Another systemwide problem is a lack of coordinated care, especially for the most seriously ill. Patients are frequently discharged from inpatient psychiatric stays without adequate follow-up.

These problems are costly for the Medicare program and its beneficiaries. But behavioral health care in the U.S. involves a complex web of payers and providers

other than Medicare, and the problems are endemic. It's important to recognize that Medicare may be limited in its ability to effect significant change.

Commissioners have long expressed interest in this topic. Since behavioral health care is the province of many and the problems are so pervasive, many of the policy levers lie beyond the reach of the Medicare program. The challenge is to find areas where Medicare might have some traction.

The staff has identified two areas that the Commission might consider. The first area -- for beneficiaries with more serious disorders -- includes policies that might improve payment and outcomes for beneficiaries who need inpatient psychiatric care. The second area -- focused more on beneficiaries with mild to moderate behavioral health disorders -- includes policies that could improve access to behavioral health services in the ambulatory setting.

Turning very briefly to policies intended for beneficiaries with serious behavioral health disorders, Medicare's PPS for inpatient psychiatric facility services was implemented in 2005. The PPS markedly changed

Medicare's payment for these services, so it altered provider incentives and thus may have affected patterns of care, including the types of cases admitted to IPFs, the services furnished, lengths of stay, and overall quality of care. Exploring changes in beneficiaries' use of IPF services -- and post-IPF services, such as readmissions and emergency department use -- could help identify weaknesses in the PPS that need to be addressed. We also could explore mechanisms to improve follow-up care for beneficiaries after they are discharged from IPFs, including pay for performance and bundling. Better coordination and management of beneficiaries' care after discharge could reduce the need for additional inpatient stays and improve beneficiaries' general health and quality of life.

Now I will turn it over to Sydney and Kate to discuss policies that could improve access to behavioral health services in ambulatory settings.

MS. McCLENDON: So as Dana just mentioned, Kate and I will discuss how to potentially increase access to behavioral health services in ambulatory settings. This could be one option for reaching individuals with less

serious behavioral health conditions.

As was mentioned earlier, many people experience behavioral health disorders. Unfortunately, most of these individuals do not receive adequate treatment, and this is especially true for individuals age 60 and older. Of those who do seek treatment, many people have begun receiving the majority of their behavioral health treatment from their primary care providers. While increased care access is a step, studies suggest that primary care providers might need more support in diagnosing and treating behavioral health disorders.

Previous research has indicated that primary care providers are not always able to detect symptoms of behavioral health disorders, and some primary care providers have said that they are not comfortable treating the complex behavioral health conditions.

One potential solution to address these gaps in behavioral health care could be the integration of behavioral health clinicians with primary care providers.

Integrating primary care providers and behavioral health providers could be successful for multiple reasons.

First, integrated care builds on an existing relationship between primary care providers and beneficiaries. Older adults are often most comfortable with their primary care doctor relative to their own providers and prefer having conditions like depression treated in a primary care setting.

Furthermore, integration increases access to behavioral health services by utilizing an existing provider. Primary care providers are already part of the Medicare system, and using them to deliver mental health services would not require the addition of a new provider category.

Many primary care providers are already asking questions about their patients' emotional health. This indicates interest in looking at health holistically in order to understand how poor emotional health might exacerbate other conditions.

Holistic health management could also potentially circumvent stigma surrounding behavioral health. If beneficiaries had all of their health conditions treated together and equally, it might reduce stigma that prevents some from seeking care.

Finally, as mentioned before, some primary care providers aren't comfortable diagnosing and treating behavioral health conditions. Collaborating with behavioral health clinicians can make primary care providers more comfortable administering needed treatment.

While multiple studies have indicated that integrated care can lead to positive patient outcomes, what integration actually looks like varies across practices. One model for integrating behavioral health in primary care is the collaborative care model. The collaborative care model involves three providers: a primary care provider, a behavioral health manager, and a psychiatric consultant. The primary care provider and behavioral health manager collaborate on care decisions while the psychiatric consultant provides weekly treatment plan reviews.

The collaborative care model tracks patient progress and outcomes via standardized tools such as the PHQ-9, which is a questionnaire that screens for depressive symptoms. Providers utilize tools like these to address treatment plans according to patient progress.

Other models vary from the collaborative care model in how they approach integration. Often these

variations occur in regard to what providers are involved and where they are located. Some models differ from the collaborative care model by only using two providers or by utilizing different providers such as pharmacists. In some practices, the primary care provider is in charge of treatment while in other practices treatment decisions are made collaboratively.

Finally, integration can vary based on whether providers are collocated or embedded. Collocated practices simply have providers in the same space. Embedded practices go a step farther and share billing systems and patient records. Regardless of the model, regular communication between team members is an important component in patient treatment.

Next Kate will discuss how integration might work within the Medicare program.

MS. BLONIARZ: There are a number of issues that would need to be addressed for Medicare fee-for-service to directly pay for these types of integrated models.

To illustrate, I'll use CMS' proposal in its 2017 initial fee schedule rule to pay for the collaborative care model.

First, how would Medicare pay for the service? CMS proposed to create new fee schedule codes, paying the billing clinician for the work of the collaborative care team.

Second, what are the requirements to receive the payment? CMS' proposal is that the payment would go to the clinicians that meet a set of new coding requirements for the specific collaborative care model that Sydney just described.

Third, are there requirements imposed on the clinician or the patient? In CMS' proposal, because it is a regulatory fee schedule action, any clinician specialty could bill for this service, and CMS has proposed no limit on the patients for which the service is covered.

And, fourth, are there additional program integrity requirements? CMS in its proposal has not set a limit on the number of services that could be billed per beneficiary per month or the duration of the service.

On this slide I'd note a couple of concerns with CMS' proposal. Again, this is their draft proposal, and their final rule will come out this fall.

First, CMS' approach codifies a specific care

delivery model into the Medicare fee-for-service payment system.

Second, leakage would be a concern, particularly for services like the collaborative care model, where the patient not may not interact with the billing clinician and therefore be less likely to perceive the benefit.

Third, the evaluations that Sydney summarized show that the collaborative care model is highly effective, but in the context of structured training in how to administer the model, and strict adherence. This goes beyond the guidelines that are generally included in the fee schedule billing for a code.

Fourth, the collaborative care model payment would be made for any covered and provider no matter their existing treatment relationship. And even if all these issues are addressed, there is the overarching issue of making sure that the service is of high value and relevant to the beneficiary. Integrated care models may be appropriate for some beneficiaries -- for example, those with moderate behavioral health needs and a good relationship with their primary care provider. But once the codes are part of the fee schedule, they can be billed

for anyone.

Another component of the ambulatory behavioral health care workforce we wanted to discuss are those services provided by behavioral health specialties. These are clinicians that specialize in mental health and substance abuse diagnosis and treatment. Three provider categories -- psychiatrists, licensed clinical social workers, and psychologists -- make up nearly all of Medicare's behavioral health specialists. The table includes the education, training, and licensure to bill Medicare in these provider categories, the type of services they commonly provide, and the number of providers and Medicare fee-for-service patients covered.

Over the coming cycle, we could also spend some time considering policies in this area. But keep in mind some of the issues that Dana laid out earlier. The supply of these services may be affected by policies and structural factors well beyond Medicare payment.

To sum up the information that Sydney and I covered, models that integrate behavioral health with primary care may be one way to improve access, but Medicare will still need to decide how to pay for these services in

a way that ensures that the resulting spending is of high value.

A second area is to consider policies for Medicare's behavioral health providers. But there are many reasons for the undersupply of specialty behavioral health services, and so Medicare's options may be somewhat constrained.

As Dana laid out at the beginning of our presentation, improving behavioral health services is a complex and multifaceted issue, and many of the potential solutions lie outside the Medicare program. What we've tried to do today is to focus on two areas where the Medicare levers are more clear: improving the inpatient psychiatric payment system and improving access to ambulatory behavioral health services.

So we would welcome your reactions to what we've presented, can take any questions, and look forward to your discussion.

DR. CROSSON: Okay. Thank you very much. We're ready for clarifying questions.

DR. REDBERG: Thanks for an excellent chapter, and I think an important topic, and you outlined things

that perhaps we could for Medicare.

My clarifying question is in the mailing materials on Table 4 where you had the three categories that you just laid out again. But I'm just curious if you could give us an idea of the relative charges or costs, whatever, for each of these HCPC codes in there. I'm just wondering. Relatively, are they in similar -- it's on page 24.

MS. BLONIARZ: Yeah. Let's see. Generally, my instinct is to say that the time-based payments are probably somewhat similar.

DR. REDBERG: Like psychotherapy would be similar to a patient visit?

MS. BLONIARZ: If it was for 45 minutes, right. But what I will say is that -- and I think I noted this -- licensed clinical social workers get 75 percent of the fee schedule rate. Psychologists and psychiatrists and any other medical doctor would receive 100 percent. So there is a difference in Medicare's payment. But, you know, I could put down what the payment rates are. That's no problem.

DR. REDBERG: Thank you.

DR. CROSSON: Jack.

DR. HOADLEY: Also on that same question about the codes, are these -- are the -- I mean, obviously, the E&M codes are used by lots of different specialties. Are the psych diagnostic evaluations, psychotherapy, do they tend to be used much at all by ECPs or other --

MS. BLONIARZ: I don't think so. I think these are pretty limited to these types of specialties, the psychotherapies.

DR. HOADLEY: And on the coordinated care, new CMS proposal, I gather from what you said that's not being proposed as a demonstration. This is just becoming a new piece of how it would work.

MS. BLONIARZ: Yeah. CMS is proposing a new set of Level 2 HCPCS codes. The services would be covered starting January 1, 2017, for every -- you know, for Medicare fee-for-service, through the physician fee schedule.

DR. HOADLEY: And did they have any estimates in impact -- in their impact statement about how much take-up of these they might anticipate? I mean, we've had so many of these other new codes that then end up having very

little take-up.
MS. BLONIARZ: They do, but I haven't looked at it, but I'll get back to you.
DR. HOADLEY: Okay. Thank you.
DR. CROSSON: Kathy.
MS. BUTO: On page 34 in the mailing materials, and the prevalence of claims identified, behavioral conditions, did we have anything for dementia or Alzheimer's disease, because you'd think, wow, that's got to be a category that -- and a growing category that we ought to be aware of.
MS. BLONIARZ: So this was deliberate. You know, there are -- we could easily present information on dementia and Alzheimer's disease incidence and spending. We took it out. We had talked about including it initially, and feel that, at this point, the topic seems so broad, and to kind of have so many different facets, that dementia and related disorders are a different disease process, it's a different age demographic, providers involved are very different. It's seemed different enough to us to kind of take it and treat it separately, and just at this point to talk about kind of mental health

disorders, you know.
MS. BUTO: A lot of which are inpatient and ambulatory as opposed to more of an institutional kind of --
MS. BLONIARZ: That's exactly right.
MS. BUTO: So I assume that at some point we'll be looking at that, because I think as we talk about integrated care, and even the dually eligible, melding the payment streams and so on, that that's a category that would fit into both those.
DR. CROSSON: I had Pat and then Bill Hall, and then Sue. Okay.
MS. WANG: So I thought this was an excellent chapter. It's so incredibly important and it is a very big challenge to figure out what Medicare, especially Medicare fee-for-service can do about this.
I was curious because I think that the change in inpatient capacity for this category of beneficiaries, and I assume that you're not -- you didn't -- substance abuse is a very big problem in this bucket of behavioral health, but are you focused on mental health or -- because you mentioned mental, or is it the whole array?

MS. BLONIARZ: So, I mean, I think this is part of what we'd like to kind of get from you, is, you know, what things seem to fit together here. We did look at kind of coverage for substance abuse and then also some of the data work that I've started. It does include that, because so many of those conditions are comorbid with mental health disorders.
MS. WANG: Yes. Exactly.
MS. BLONIARZ: There are very special policy challenges in substance abuse treatment, mostly around data sharing and privacy of records and things like that. But we had -- we hadn't excluded it and that's part of why we used the phrase "behavioral health" versus "mental health."
MS. WANG: Right. Okay. So in the focus on sort of maybe trying to -- sort of make the inpatient psych reimbursement better -- you know, that's good because that's always a good thing to do. I think that there are a lot of reasons, maybe, that inpatient capacity has decreased over the years. The thing that you were touching on, which was integration, is very important, though. I think that that's the key, the core, and not necessarily, hopefully not an inpatient kind of focus.

Do you have specific ideas -- as you think about improving the IPF, do you have specific ideas for an updated system that would include, for example, follow-up care within seven days? I don't know if there are readmission measures right now for psych. I don't think so.
MS. KELLEY: No. So this would be the start of exploring many of these issues, including even getting a handle on what the readmission data look like. Of course, there are both medical and mental health readmissions that would need to be considered. But so this would be starting to explore all these issues and thinking about how we could encourage better follow-up care, better coordination. So that could include readmission measures, penalties. We could also consider whether there were opportunities to, say, bundle post-discharge visits with payment for the inpatient stay. These are a number of things we could look at.
DR. CROSSON: Bill.
DR. HALL: This is certainly a major, major, major problem, and one approach that a lot of communities have taken is to not look at integrated teams, individuals

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who would be available, but to look at more at what I guess we would broadly call successful group therapy. Do you find any data on that approach?

MS. BLONIARZ: No. Medicare does cover group therapy and it's often provided in partial hospitalization programs. I don't think we have a good handle on how well it works in Medicare fee-for-service, though.

DR. CROSSON: Okay. Sue.

MS. THOMPSON: Two questions. You mentioned physician, psychologists, and the social workers as the three categories. Is there anything in here that restricts your psych-certified nurse practitioners from playing some role here? I mean, I think they're included as well.

MS. BLONIARZ: Absolutely.

MS. THOMPSON: Okay.

MS. BLONIARZ: Yeah. I should be clear. I pulled the specialties that have a psychiatric focus, and, unfortunately, in kind of Medicare's claims processing, I only know that somebody is an advanced practice registered nurse. I don't know if they're psychiatric --

MS. THOMPSON: -- certified.

MS. BLONIARZ: Yeah. That's right. But

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absolutely they would be part of it and, you know, they're covered like any other nurse practitioner would be.

MS. THOMPSON: Well, and it's a lead-in question to my next question, which is, somewhere between 14 and 20 percent of the Medicare beneficiary population have a claim related to behavioral health. Is that how I'm understanding that opening?

MS. KELLEY: No. That's an estimate from the National Academy of Medicine. Work that we did ourselves -- are you getting your hands on -- it's Table A1 on page 34. So --

MS. BLONIARZ: I'm not sure we'd want to just try to come up with it. You know, you have 15 percent of Medicare fee-for-service beneficiaries with a claim indicating a depression diagnosis. Like that's one number. But we could get you kind of an unduplicated number.

MS. THOMPSON: It's a number that is worth paying attention to.

Of that number, do we know how many of those patients do have dementia diagnosis, how many have SPMI diagnosis versus depression/anxiety diagnosis? Because I think we would think about how to care for those very three

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-- they're very different types of populations -- in very different ways, from the standpoint of just care strategies. So I don't know if that is available, if that could be available, but I would think that would be helpful in terms of understand what and how policy should shape.

MS. BLONIARZ: And I think -- right. This goes to the point that we've struggled a bit with getting good, reliable data. CMS creates chronic condition flags that make a lot of data analysis much easier. And I would say that they're -- the number -- the types of information they have for these kinds of conditions lags behind other medical conditions. But I do hope to come to you with information on, you know, what do we think are kind of, you know, people who have a moderate behavioral health need versus people with a seriously persistently mentally ill kind of population.

DR. CROSSON: Okay. So just to paraphrase a little bit, if this is behavioral health, and this is what the health care system can do about behavioral health, and this is what the Medicare program can do about behavioral health, and these are not proportionate -- there's no value judgments; it's just the positions my arms take -- what we

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have here are, I think, two well-thought-through notions about how we, at MedPAC, could help the Medicare program, through its payment system, improve the situation that exists, at least marginally. One is through payment for inpatient psychiatric care and the other one is through perhaps an improvement payment for care coordination, emphasizing team-based care of patients with behavioral health problems.

So that being said, I think what we would want to have in the discussion is maybe two-fold. Number one, are these the right two things to be working on, or does someone have an idea that we should be working on something else, other than these two. Absent that, what do you think about these two proposals? Are they things you can support, and how are -- could they be improved in some way?

And we have -- we've got -- so we've got, from this morning we've got Bruce and Craig, who have volunteered to start off.

Bruce, you're looking surprised.

[Laughter.]

Craig.

DR. SAMITT: I'm happy to go first. I do think

both of these areas are a good place to start. You know, to your point, Jay, I think this is an area where we've truly failed Medicare beneficiaries, we've failed, I think, all patients, in finding a solution to the behavioral health crisis. But I do think this is as good a place to start as any.

I want to concentrate my remarks on ambulatory, because in addition to the concepts presented, I do wonder whether there are two other channels that we could consider. One is, you know, going back to the discussion we had earlier about ACOs, and whether there is some mechanism, either through quality metrics, incentives, or even flexibility in the ACO environment to really integrate medical care with behavioral health, and whether there's a way to explore opportunities there.

You know, I would venture to say that if you look at how MA plans manage behavioral health, it probably is quite different than what you would see in fee-for-service, and is there any way that we can integrate some of those methodologies into fee-for-service through the ACO program?

The other thing I was surprised not to see mentioned, which is another topic we've discussed

previously, is the whole notion of telehealth, and the role that telehealth can play in managing behavioral health. You know, I think there are many who believe that, for multiple reasons, telehealth is a really good option in behavioral health, from both an access perspective, because it's certainly virtual, from an expertise perspective, because you're more likely to find available clinicians who can meet the beneficiaries' needs, and also from a stigma issue, you know, in terms of the fact that telehealth, either through avatars or other solutions, may make adherence to behavioral health treatment a bit easier.

So we've talked about sort of paving the path for better coverage for telehealth in prior meetings and this may be an area where we very much want to accelerate that thinking.

DR. CROSSON: Bruce, did I get it wrong or right, that you wanted to weigh in initially?

MR. PYENSON: I wanted to weigh in second.

DR. CROSSON: Second. Okay.

[Laughter.]

DR. CROSSON: You've got it.

MR. PYENSON: Thanks.

[Laughter.]

MS. BUTO: You got your wish.

MR. PYENSON: So I think the -- my interest would be on the ambulatory side, and I'm just wondering if there's a -- the value or the danger of not including dementia and Alzheimer's in the discussion, if it really is such a separate issue. And I think it's going to be on us faster than some may think, looking at the drug pipelines that are coming, addressing amyloid plaque and things like that, that this might be on us pretty fast.

So those are my comments. Thank you.

DR. CROSSON: Thank you. Okay. So let's open it up. Let me see hands for people who wish to comment. A fair number. So I'm going to start -- go back to what we did originally and start over here with Brian and go down this way.

DR. DeBUSK: Just four things come to mind, as I was reading through the summary earlier and listening to the presentations. I do think there's an opportunity to move to a stay-based payment system on the inpatient side. You know, I just -- I see the system described in the mailing as older technology, in terms of payments.

And I'm also very excited about this behavioral health integration, the cooperative care management model. It sounds like it addresses a lot of the issues that we face.

But I noticed, on page 20 of the mailing, there was one thing that got my attention. Have you guys mentioned it? Bundles. And I would be interested in looking at some type of, say, a BPCI-type or some type of model. I know these aren't perfect for bundles. I mean, these aren't like a joint or something like that. But to the extent that we could use that bundle to coordinate the inpatient stay with the post-acute care, because one of the things that really jumped out at me was it seems like we have a lot of problems with that handoff. And even if the cooperative care management model and the new CMS codes, even if that addresses more of the outpatient and non-acute, non-inpatient need, I worry that that handoff still isn't in place.

And so while I wouldn't want to go just episodic care crazy in this area, I do think this might be an area that bundles would benefit.

And then the final thing, and I realize this is

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somewhat beyond the scope of us and Medicare, I do think we should circle back and look at the provider shortages, because I do think even with behavioral -- this novel solutions, again, engaging primary care, I worry that all we're doing is delaying the inevitable if we don't go back and bring more psychiatrists and psychologists online.

And that's all.

DR. CROSSON: Thank you. Alice.

DR. COOMBS: So a few years ago I had the opportunity -- and I think it was around 2010, 2011 -- to go to a psych hospital and spend the day with one of my colleagues. And he actually talked about how they had global payment, and it was operated through the states, located in Jamaica Plain in Boston. And you might take a look at this because it's -- I think it really is a good example of how you can integrate outpatient and inpatient.

And it was amazing because when a patient left their facility they had a day program that was kind of like a bridge, so that you wouldn't just be -- you wouldn't just depend on them being hooked into a clinic. They would come back and participate in the day program. They had a, you know, a near 100 percent follow-up because they knew the

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people that left, and that was part of their quality benchmark, that there was a follow-up for a day program at that same facility where they were discharged.

Now, they had a limited number of inpatient beds, and so the rate-limiting step was if you could have the contact to get into the hospital in the first place, during your acute phase of your illness, and it was located right outside of Brookline in Jamaica Plain, which meant that automatically, you know, you have a different type of patient clientele there. I mean, you have still mental health issues but -- and when you talk about socioeconomic status, it's really -- you're really screening for some very different types of patients with those mental health issues.

So if you could look at that and see how they did it. But it was interesting in that they had a transition period between the inpatient and the ambulatory, which proved to be successful for them. And I don't know how that works, but from my standpoint -- I'm a hospital-based physician -- I see the inpatient as a really important issue, the point of entry, where there's depression and there's attempted suicides, and there's substance abuse.

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So right now, in the ICU, someone can come in that's unresponsive, and I'll do what's necessary to get them extubated and awake. I actually have to wait for a nurse practitioner -- a psych nurse to come in to evaluate them, even for placement, even for the next stage of the transition.

So I think the workforce -- and we rarely have a psychiatrist that comes in. It really is a nurse practitioner, a psych nurse that comes in and evaluates them. So right now the workforce is an issue. So I would think that any kind of creative, you know, telemedicine or any of those things are going to be important, even to the point of follow-up and transitioning back into the community.

So I think the transition period is really huge. We don't talk a lot about transition for psych patients, but it's huge for mental health, and in that one- or two-day period you can relapse and they're back in the hospital, and they get a full course of hospitalization, because there was a lack of follow-up. So I think the lack of follow-up is really key.

But, you know, and I would hope that we could

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look and tease out how much of the inpatient hospitalization is related to substance abuse? It could be related to depression and all those other things, but just substance abuse -- medication-related hospitalizations -- with mental health, because I think that's really important.

And just one other thing. So I worked on a task force in Massachusetts and we actually looked at mental health beds, and we looked at the distribution of where the beds were, and we looked at where the population was. And I don't know if that's something that's possible, but certainly if one region of the country was more adversely affected by the lack of inpatient beds, then that would tell you that this is really a pressure point for, say, if it was in Mississippi, that they have, you know, next to no mental health beds, so that that becomes a problem in terms of what you see with the whole outcome and inpatient hospitalization.

DR. CROSSON: Thank you. Jack.

DR. HOADLEY: So my interest is particularly in the integrated ambulatory approaches, and I've had the good fortune to go on some site visits, more on the Medicaid

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side of the world, although also on the dual stuff, where we've talked to clinics and things that use this kind of approach. So, I mean, I came away very impressed with that team-based approach, and one of the things that I know got talked about was that once they operate in this approach, the primary care clinicians learn more about diagnosing their patients and screening for depression and so forth. And you talked a lot about some of the discomfort that some of them have in their ability to do this effectively. And one of the benefits of this team approach is when the primary care providers get better at that and more willing to do it, and then make, you know, the warm hand-offs, as they call them, to the mental health professional that's part of the team all in the same day. I know on Medicaid one of the issues has been the ability to pay the second provider on the same day, and, you know, so there have been efforts to try to deal with that.

So I guess some of the questions I have as we go forward is, you know, you talked about this new CMS model and some of the limitation, and it clearly doesn't go in all the directions that ideally we would want. On the other hand, I suspect to do it within the fee-for-service

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model would start to be just loaded down with all kinds of rules and regulations, and then it would just not happen.

So I don't know if we can try to come up with any ways to fine-tune what CMS has come up with to improve on some of it. But I would also be interested in knowing what Medicare Advantage plans are doing for these comparable kinds of situations. I assume a lot of them are going in and certainly -- I would be almost certain that some of the integrated plans, you know, immediately go into these team-based approaches. But even what are they doing within the less integrated Medicare Advantage models where they still are dealing with individual providers and that they come up with payment mechanisms, bundling mechanisms, whatever, to try to encourage this team-based approach. And, obviously, the same with the ACOs. Are any of them trying things sort of within some of these things we talked about this morning, the later options of some kind of capitation payment or other kinds of things might be necessary before you could do anything that kind of breaks out of the box that we can do. But at least if we saw some examples particularly in these sort of -- not so much the fully integrated MA kind of approach but the less integrated or

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the ACO, maybe there's a way to generate a concept that we could bring back and use more broadly in the fee-for-service.

So I think it's a really worthwhile kind of direction to try to think of, but I also appreciate there's a lot of problems getting there. So I hope we can find some creative ideas on it. And the dual demo would be another kind of place because, again, they presumably have a lot of these people, and I don't know whether any of them have particularly gotten in and started to come up with solutions. So add that to the list as well.

DR. NERENZ: This is not well thought out. It was prompted by what Craig said about the two things on the list perhaps not being sufficient or we could think of some things in addition.

I have been looking at the tables on pages 36 and 37 of the chapter and the text on 37, and it seemed interesting that we're looking at prescription refills for patients. We're seeing patients with schizophrenia or beneficiary with schizophrenia are getting like six refills each month, others getting five refills. That's a lot going on. And then the text on the next page says, well,

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70 percent of the beneficiaries aren't getting antidepressants or antipsychotics. So these drugs are something else for the most part, which just led me to think in general that something in the domain of care coordination, maybe medical home is an avenue to look at just because there seems to be a lot of medical things going on in these people that we've identified by virtue of the psych diagnosis. And then just to play off Craig's comment, those things are not necessarily just more psych visits. These things are kind of different. Maybe community health worker programs may be something.

Okay. So then from that point, I said, well, maybe there's an analogy here to the PACE program where you've got people with some Medicaid paid services going on, apparently a lot of them, given the number of drug fills. But then you've got some psych services, and we may have people leaking over into sort of the community support social program domain that's paid either by Medicaid or perhaps some other state program. And maybe there are some opportunities to do something like PACE where the thing to be created would be a daycare -- that kind of program, and it would be neither of those two things.

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And then, finally, ending up with Jack, I said, wait a minute, the duals demo. A whole bunch of these people are dual eligibles, and the dual demos presumably are setting a framework formally for combining some of these payment streams. It's done differently in different states. And maybe they're doing some of these things already.

So I ended up kind of with where you ended up, that we should at least be looking at that and seeing what's going on.

DR. REDBERG: So building on David's comments, you know, I think depression obviously is a big problem in general and in the Medicare population, but it's very intermingled, I think, with loneliness and exacerbates a lot of other problems. And there are other things, I think, that we could do because, you know, at the same time I think we're overdiagnosing depression and certainly there's a lot of data that we're overusing antidepressants. You know, when I looked at this Table A.5 that you just referred to on page 37, I thought, you know, every one of those drugs has so many side effects, and data repeatedly shows that, you know, particularly in nursing home patients

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but also just in ambulatory elderly patients, these drugs are overused and cause big problems.

We just published in JAMA Internal Medicine last week that in the teachable moments the overuse of antidepressants in the Medicare population because of the side effects from it, a woman who's a family member had passed away, so grief would be a normal response, but was given an antidepressant and had very untoward side effects, SIADH in this case. And it says one in five antidepressants is overuse, and I think it's probably higher, you know, for these medications here. And we also know that even without isolating antidepressants that our elderly are on more and more medications, which can also lead to sort of dulled cognition and depression, and that just sort of weaning Medicare beneficiaries off the increasing number of medications they're on for very unclear reasons, where that gets started and don't get stopped. A colleague just told me yesterday, he's been telling me for like the last two years that he's worried his father is developing dementia, his elderly father, but he was also -- which he didn't even think about -- getting a fentanyl patch for some nonspecific pain. And, of

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course, the pain, as it often does, wasn't getting better, so they kept upping his fentanyl patch, and they finally just stopped the fentanyl. He suggested just stop it, and he said his father is now alert and the dementia is gone.

You know, I just think that kind of thing -- you know, we have a tendency to medicalize depression, and just a lot of our antidepressants are used inappropriately. Even the diagnosis is inappropriate. That's why I was kind of interested in what the payment was for the cognitive codes. And, you know, it doesn't even have to be psychiatrists. I think, you know, just kind of group therapy -- I mean, I always encourage, and I'm sure you do, too, my older patients to just go out and do things, you know, go to senior centers, see other people. I mean, there's a lot of value to very simple things, get engaged, volunteer, you know, because just getting people out I think reduces the depression and those symptoms from it. So I'd like to build that into our plans for approaching this.

DR. CROSSON: Comments?

MS. BUTO: I'm just going to build on what Rita said, and I think Jack -- I can't remember -- Jack and

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Dave, that I really do think in addition to these two bullet points, if we could add something about medication management of mental health drugs in this population as part of our overall -- since we're focusing on drugs and population health. And then the fourth bullet would be something about improving the connectivity between Medicare and Medicaid financing and coordination for the dually eligible since Medicaid provides so much of the financing for care for the population.

So I think the two would be very helpful in addition because this sounds like it's a little too skimp -- I mean, as important as inpatient and ambulatory is, that it doesn't really cover the whole universe.

MR. GRADISON: It comes as no surprise to comment that you can't pick up a paper today without seeing an important article related to this general subject of overuse of opioids, suicides in the VA, the interaction between police and the public through the criminal justice system, the high rate of behavioral health issues in the prison population, and on and on. But you very seldom see a lot written -- I don't say it's zero -- about the prevalence of these conditions and the concerns about them

involving the elderly and the disabled. And it seems to me that this may just be an issue that the Congress might be taking a look at as they're looking around for useful things to do. And I am concerned --

[Laughter.]

MR. GRADISON: I couldn't help it.

DR. MILLER: As only you can say.

MR. GRADISON: It seems to me that we should be thinking about putting a section, a chapter in something as soon as our June report, even if it doesn't have any specifics, just to lay out the issues. And most of that is already written. Yes, it's somewhat strategic, but my real concern is that if they do something -- and think about the growing concern that it's really -- I'm not talking about political issues so much as just if you look at who's saying what, it's a broadly shared concern that something should be done. And I think by putting out a chapter that might become public in June, we might in effect be saying don't leave out the elderly and the disabled from your consideration. That would be the message. We wouldn't say it that way, of course. And by that time, we might be able to get much further along in some of the specifics so that

if somebody in their wisdom were to invite our leadership up there to comment, there might be more specific comments than we're in a position to make at this time.

DR. HALL: I agree with a number of the comments that have come forward here, but specifically that concentration on the ambulatory side may be the most productive use of our funds and the very scarce talent that's out there.

I also agree with what Brian mentioned about the incredible lack of available manpower in the United States for dealing with any sort of behavioral disorders. I believe it's accurate to say that in the last five years, the numbers of certified psychiatrists that have been trained would be at the very top 20 for the whole country and more like 12. It's not an area of medicine that attracts really good people. A lot of that has to do with the perceived lack of financial reimbursement, but a lot of it is more that it doesn't seem to be on the radar very much. And those that do get trained tend to concentrate themselves in institutions, so the community is really where I think the action is.

And when we talk about integrated care, I hope

we'll take a very careful look at integrated care that can deal with volumes of patients, so group therapy, services in places where older people congregate, various community centers, that sort of thing. I think that's really where the action is and would be the most bang for the buck.

But I just want to say a word about why I worry a little bit that we're excluding Alzheimer's disease. I know that that's like, you know, swallowing a huge pill, but just a couple of quick statistics if I may. The prevalence of Alzheimer's disease right now in the American population for people in their 70s is about 15 percent, some form of cognitive disorder. In the 80s, it jumps to about 35 percent. And above that it's a slight majority of people. So this is not an incidental little disease that's hanging around here. And while we all hope for a cure tomorrow or the next day, we better be prepared for a long, long slog before that disease goes away.

So that brings to mind to me that we ought to take into account what is the short history of, the natural history of Alzheimer's disease. On average, it's about seven years of symptoms before it becomes either the major cause of death or leads to some other form of death closely

related. In those seven years, the vast majority of time will be spent in the ambulatory sector. And while the specter of the demented patient in the institution tugs at our heart strings, it really isn't a very terminal stage. In the meantime, these are people that who are passing you in your car. These are people who bump into cones at the grocery store. These are people who leave stoves on, who disrupt family relationships in very subtle ways, mainly because of associated psychiatric disorders which are treatable, particularly require expert people.

So I think somehow if we can sneak into this whole Alzheimer's thing, not the institutional ones where I would agree bang for the buck there is going to be fairly modest, but I think taking these ideas in that direction would be a huge, huge boost in the quality of care for older adults.

DR. CROSSON: Thank you, Bill

MS. THOMPSON: I'll comment, but briefly, on those two areas of consideration.

On the inpatient side, I had the unfortunate experience of being part of closing an inpatient psych unit, and the next closest inpatient psych facility in that

part of Iowa was 70 miles away. We didn't close because we couldn't make money in inpatient psychiatry. We closed because we were down to one psychiatrist, and he couldn't cover the emergency department 7 by 24. So the manpower issue is, I think, many, many, many times related to why we don't see the availability of inpatient psychiatry. But I think we've made a good point here about the need to think more about what do we do with our manpower deficit and caring for these patients.

On the ambulatory side, which I do find much more hopeful, particularly around our Medicare population, within the ACO discussion we had this morning, we have had an integrated health home model, which is a medical home model, integrated ambulatory care, community-based mental health program with our ACO, and have seen some really positive results. I would be delighted to share some of that at some point in time. But, nevertheless, I do think that integrated health home model is very, very positive.

Now, the next comment I'm going to make, I'm not even sure MedPAC has authority to speak to this, but one of the obstacles in that integrated health home model or any model which has primary care and psychiatry attempting to

care for a patient together is the rules around privacy, and the primary care physician or provider not being able to even review the consulting comments by the psychiatrist.

So if we're really -- if we want to take on the stigma issues, if we want to take on and be very serious about caring for in a holistic way these issues for our Medicare population, the privacy issues remain a huge barrier.

So, with that, I'm delighted we're having this conversation, and I just really encourage us to stay after it.

DR. CROSSON: Thank you, Sue.

DR. GINSBURG: I'm very enthusiastic about our getting into this area. Perhaps we can get specific recommendations, but even if we can't, I think it will be helpful.

I was listening very carefully to Sue's description about the closing of the psychiatric unit because I certainly have noticed this happening. I was concerned that our inpatient acute payment system, you know, leads to relatively unprofitable payment rates for psychiatric admissions, and that may be the case. That's

probably something that's really within our bailiwick to come up with some suggestions to fix.

In site visits, I also had heard a lot about the issue Jack brought up in Medicaid about the prohibition against two E&M services in a day. One could be a behavioral health service. Is that an issue in Medicare as well?

MS. BLONIARZ: I don't believe it is, as long as there are two different providers.

DR. GINSBURG: Okay.

MS. WANG: So, you know, we have a very large dual-eligible population in our MA plan in integrated products. We're in the duals demo. We also have a very large Medicaid program that is -- where our state through waiver programs is trying very hard to foster a very comprehensive, you know, completely integrated model for folks with serious mental illness. So I would be happy to tell you what that's about, and I'll tell you in about a year how it's going, because it's a lot.

I just want to share a couple of the challenges, I think, for the population. So, you know, the financing and integrating the financing is very, very important, but,

you know, the delivery system, if you will, for the population is much more complicated to find and to put together. Many of the most important people are non-billing entities. They've been grant-funded through state mental health programs, through federal programs. They are unconventional in our -- and one of the advantages, I guess, about being an MA plan is that you have the money so you can decide who you want to pay. So we will use nontraditional providers like peer bridgers and health homes and what have you. You know, there's just a lot more flexibility.

I mention this because I think that it is worthwhile. You've observed things for the inpatient psych system, and I'm always in favor of, you know, making things better. So if there are improvements to be made, I think you should go for it. But I think that the goal of that should be less about -- payment accuracy is really important, but the second part, which is, you know, our emphasis and I think that everybody's emphasis who's working in this area is to reduce inpatient utilization and increase ambulatory. That is always the expectation. You are reducing inpatient for psych as well as medical, and

you're increasing things that go on in the community, including paying for supportive housing if you need to.

So I think that one of the goals when you look at updating the inpatient psych system is not to -- you know, by greater efficiencies, and as days come down, is not to lose the money but to find a way to translate that into the next step of getting people back out to the community with the resources they need, whether that's a bundle or something else. I would not be in favor -- the reason I asked about readmission measures was not to suggest that folks be penalized, because I think that a big problem with the population in general is that there are very few resources. And, you know, sort of readmission -- I think follow-up ambulatory care is very important. Readmission measures, though, may be more difficult to hold an inpatient facility responsible for if they don't have a place to -- I mean, there are limited numbers of transitional housing spots. They tend to not be transitional. After awhile, people just wind up staying in them, and it's really a problem.

As far as coordinated care is concerned, absolutely. The couple of observations that I would share

is I don't think that coordinated care really means physical collocation. That could be the manifestation of it, but you can have physically collocated providers who are not communicating with each other, and that doesn't work. I mean, the goal is communication, and I think that it happens physically collocated, it happens through technology, it happens through cloud-based shared care management systems that bring in, you know, health homes and community-based providers. With clinicians, I think it's a very important area to be looking at. The challenge is that the most effective providers, if you will, in the system are not billing anybody, and they're critically important for the population.

You know, the Medicaid home and community-based waiver program supports a lot of these types of providers, so just in terms of greater familiarity it might be something to look at.

So it's obviously not a specific set of suggestions, but I think that's the landscape, I think, of what needs to be looked at.

DR. CROSSON: Okay. Thank you, Pat. This has been a very good discussion. I did hear a significant

consensus or close to consensus around focusing on ambulatory care as opposed -- not necessarily opposed to, but as being more important than dealing with the issue of how inpatient psychiatric beds are paid for, not that we would necessarily ignore that.

And I also heard in different ways significant concern about the availability and adequacy of providers for behavioral health. While we can't necessarily influence that directly, we can have something to say, I think, about the payment system.

I have to say, you know, at least during the times that I've been on MedPAC, we've tended to, you know, kind of include psychiatrists in with other "primary care physicians" or physicians who are being primarily paid through E&M visits. And, you know, maybe there's some work here to think, you know, harder about who are caring for patients with behavioral health problems, to what degree we can learn a little bit more about that and to what degree we think, or don't, that the Medicare program or MedPAC specifically could act in some way to improve the availability of caregivers.

So I would say in terms of have we added an

emphasis, yes, we have. And have we added a new piece of work? Easy for me to say, no offense intended, I think so. So thank you for this good work, and we'll be looking forward to hearing more.

MR. PYENSON: I heard a lot of interest in Alzheimer's.

DR. CROSSON: Yes, indeed.

MR. PYENSON: And I know from several people here in several different ways, you know, I think Bill Hall did a very nice view that Alzheimer's manifestations can be in depression, anxiety, and other things. So I wonder if we could add that to your list.

DR. CROSSON: Yes. I'm sorry. I didn't mean to ignore that at all. I think we have a decision to make as to whether or not to take on Alzheimer's and dementia as part of this work or as a specific piece of work, and I will leave that to Mark to work out. And, Jon, you have an idea?

DR. CHRISTIANSON: No, just another decision to make. I think it was Kathy who mentioned the issue of medication management. And I think that's in our purview.

I think we have data, and I think it could be folded into the outpatient ambulatory care topic. But I think it's really important not to lose it.

DR. HOADLEY: Yeah, I wanted to follow up on that point just briefly, too. One of the things that brought it to my mind is that we do have a medication therapy management requirement on the Part D side, one that, you know, the Commission has looked at from time to time and that generally the look has suggested that it's not operating as well as people would like it to, and there are some CMS demos -- a CMS demo in place on it. But it does bring that to mind, the notion that that is one location. I would wonder whether the Part D plans -- how well versed they are in some of the particular issues around mental health issues and mental health implications of drugs or the use of mental health drugs, as well as -- and maybe it goes back to a question of whether there's -- you know, is there a different way to deal with primary care providers in doing comprehensive medication reviews and sort of where would that -- I mean, where would that fall? Obviously, they can do it to some degree within the scope of a normal E&M visit. But, you know, is there a way to encourage

that? So maybe that's another angle to think of on the medication side.

DR. CROSSON: Okay. Great.

MS. WANG: Just on that point, it goes without saying that if we were to look at that and make judgments or evaluations, this is all about SES. So I just -- you know, when we look at adherence rates and -- I'm not kidding. This is like a big deal, so I'm just mentioning it.

DR. CROSSON: A good place to end. Okay. Well, thank you very much. Great presentation, great work. We are looking forward to more.

Okay. We have come to the end of the day and the end of this session, and the time for the public comment. And I see one individual so far at the microphone. So I will ask you, please, to identify yourself and any affiliation you have. Please limit yourself to 2 minutes. When this light comes back on, the time is up.

And just to note that there are other ways to provide input to MedPAC staff and the Commissioners through the staff, through the website, particularly if your interest is to have that information provided before our

deliberation, so please proceed.

MR. GORDON: My name is Stuart Gordon. I'm with the National Association of State Mental Health Program Directors. That's the association of directors of State mental health agencies in the 50 States and Territories.

And let me just raise one more issue that wasn't addressed today that I think should be addressed. Two-thirds of the State Medicaid programs cover peer-support specialists. DoD covers peer-support specialists. VA covers peer-support specialists. TRICARE covers peer-support specialists. The only program that doesn't cover peer-support specialists is Medicare fee-for-service.

Now, those folks provide great services. First of all, in every State, they're certified so that they are -- but they've also got lived experience, which helps them deal with the various issues that the patients are dealing with. They help the patients deal with compliance. They resolve isolation problems. Transition was mentioned here. They help with transitions from the institution into the ambulatory setting and without the question of whether or not the individual is being isolated in a D treatment setting. There are so many reasons to include payment for

peer-support services under Medicare fee-for-service.

MA. Some MA providers do provide peer-support services. Not all of them do. We recommended to the Finance Committee Work Group that was looking at chronic care last year that they cover peer-support services for fee-for-service under partial hospitalization and under managed care as a supplemental benefit. We would urge the Commission to look at this issue. Thank you.

DR. CROSSON: Thank you.

Seeing no one else at the microphone, we are adjourned until 8:15, tomorrow morning.

[Whereupon, at 4:35 p.m., the meeting was adjourned, to reconvene at 8:15 a.m., Friday, October 7, 2016.]

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MEDICARE PAYMENT ADVISORY COMMISSION

PUBLIC MEETING

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

Friday, October 7, 2016
8:16 a.m.

COMMISSIONERS PRESENT:

FRANCIS J. CROSSON, MD, Chair
JON B. CHRISTIANSON, PhD, Vice Chair
AMY BRICKER, RPh
KATHY BUTO, MPA
ALICE COOMBS, MD
BRIAN DeBUSK, PhD
PAUL GINSBURG, PhD
WILLIS D. GRADISON, JR., MBA, DCS
WILLIAM J. HALL, MD, MACP
JACK HOADLEY, PhD
DAVID NERENZ, PhD
BRUCE PYENSON, FSA, MAAA
RITA REDBERG, MD, MSc
CRAIG SAMITT, MD, MBA
SUSAN THOMPSON, MS, RN
PAT WANG, JD

AGENDA PAGE

P R O C E E D I N G S

[8:16 a.m.]

DR. CROSSON: Okay. Good morning. I think we can begin. Welcome to everybody.

We're going to start out the day with a presentation on quality measurement and implications for our ongoing evolution of thinking about what we're calling for these purposes "premium support." Ledia and Carlos are here, and who's going to begin? Ledia? Thank you.

MS. TABOR: Yes. Good morning. Today Carlos and I will present ideas about how the Commission's concept of comparing quality across Medicare for Medicare Advantage plans, accountable care organizations, and fee-for-service could be applied to a premium support model in which there are financial rewards for higher quality.

Today's presentation is the first of a number of discussions the Commission will have this meeting cycle about issues to consider in designing a premium support model. This presentation is exclusively about how to make sure high-quality care is rewarded and beneficiaries have incentives to choose higher-quality care.

First, we will review the Commission's

alternative concept for measuring quality in Medicare. We'll then identify quality measures that can be used to measure quality across plans, ACOs, and fee-for-service in local market areas. After discussing how to reward organized health care entities for high quality, Carlos will discuss plan standards for auto-enrollment in a premium support model that rewards quality. Finally, we'll lay out some specific issues for today's discussion.

In the June 2014 report to the Congress, the Commission put forth a concept for an alternative to Medicare's current system for measuring the quality of care provided to the program's beneficiaries. The Commission has become increasingly concerned that Medicare's current quality measurement program was becoming "over-built" and relying on too many clinical process measures that are, at best, weakly correlated with health outcomes.

Under the alternative policy, Medicare would use a small set of population-based outcome measures and patient experience measures to compare the quality of care under each of Medicare's three payment models in a local market area. Please note that during today's discussion we use the term "local market area" which is the same the

geographic unit we have used in previous premium support discussions. These market areas best match insurance markets served by private plans.

The Commission has stated that the population-based outcome approach could be useful for making payment adjustments within ACO and MA models. However, this approach may not be appropriate for adjusting fee-for-service Medicare payments in an area because no entity accepts responsibility for the care of a population of beneficiaries. So current provider quality measure programs, such as the hospital value-based purchasing program, continue to evaluate fee-for-service quality.

As we'll discuss through the presentation, policymakers will need to work through some issues on how to apply this new quality approach to a premium support model.

In the June 2014 report, the Commission presented a small set of population-based outcome measures, calculated with administrative data, that could be used to compare quality across Medicare payment models. CMS could calculate measure results for each MA plan using the encounter data that plans currently report to CMS. They

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could also report -- or calculate measures for ACOs and fee-for-service using the claims data CMS currently collects.

The first four measures shown on this slide are outcome measures that the Commission currently tracks to identify the poor care or missed opportunities to better coordinate care in the Medicare program. These measures are potentially preventable admissions and ED visits, mortality rates, and readmission rates.

The fifth measure -- Healthy Days at Home -- captures the number of days within a year that a local area's beneficiaries are alive and did not have interactions with the health care system that imply less than optimal health. We plan to present an update on this measure during next month's meeting.

Last is a measure that was not included in the June 2014 report as a measure to compare models across Medicare. Low-value care is the provision of a service that has little or no clinical benefit, or care in which the risk of harm from the service outweighs its potential benefit. The Commission's work to date has looked at individual low-value measures, such as PSA screenings,

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imaging, and surgical procedures. If the Commission is interested, we could explore creating a composite measure of low-value care to evaluate fee-for-service and MA plan quality in a market area. We know that there would be some issues to work through in developing this composite measure such as small numbers and proper risk adjustment.

In addition to the outcome measures drawn from administrative data, the Commission has also expressed interest in using patient experience to evaluate the quality across models.

The Medicare Advantage and fee-for-service Consumer Assessment of Health Providers and Systems (or CAHPS) surveys ask the same questions (for example, rating of health care quality, getting needed care, and care coordination). The ACO CAHPS survey items are different than MA and fee-for-service, but the three surveys measure generally the same concepts such as getting appointments and care quickly.

In the alternative quality model, MA plans, ACOs, and CMS could continue to collect CAHPS results, but would need to change their current data collection unit to the local market area level. Some work may also be needed to

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test the comparability of measures from the ACO survey to the MA and fee-for-service surveys.

The following example describes the Commission's 2014 alternative quality model that we have described over the past few slides.

We have a Market Area A--the black rectangle.

We also have ambient fee-for-service or the ACOs plus fee-for-service Medicare quality, which serves as the quality benchmark, or reference, for MA plans and ACOs in the area, this gray box. This benchmark was established to create an ongoing incentive for the ACOs and MA plans in a local market area to continue quality improvement over time.

In this model, we then compare ACO quality and MA plan quality to the benchmark, and higher-quality ACOs and plans can be rewarded.

As a reminder of how payments would work in a premium support model, private plans state their bids for providing the Medicare benefit package to a person of average health, and these bids are combined with the fee-for-service bid to determine the government's contribution towards a beneficiary's health care costs in the specific

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market area.

The fee-for-service bid is the average projected fee-for-service expenditures for the bidding year. The government contribution in the market area could be the median bid, as in the Commission's most recent analysis of scenarios. A beneficiary choosing a plan that bid above the government's contribution level would have to pay a premium to join such a plan. A plan bidding at the government contribution level would have no premium, and plans with lower bids would give enrollees a cash rebate.

As mentioned at the start of the presentation, it is important to include quality in the premium support model so that beneficiaries have an incentive to chose the highest-quality option. One way to include quality is to vary the government contribution based on quality, using fee-for-service as the reference point.

Here is an example of how we could use quality to reward plans and ACOs in a local market area.

We again have Market Area A -- the black rectangle.

Using population-based outcome and patient experience measures, we measure the quality of ambient fee-

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for-service -- the gray box and dotted line -- and that serves as the benchmark or reference point.

We then determine the quality of the three plans and one ACO in the area.

Plans 1 and 3 have higher quality than the fee-for-service benchmark, so they are rewarded with an increased federal contribution, which would lower their beneficiary premiums and potentially increase the number of beneficiaries selecting their plan. CLICK

The ACO and Plan 2 have lower quality than the fee-for-service benchmark, so they are rewarded with an increased federal contribution which would lower their beneficiary premiums and potentially increase the number of beneficiaries selecting their plan. The ACO and Plan 2 have lower quality than the benchmark. They would receive financial penalties through reduced federal contribution, in the case of a plan, and for ACOs a reduced expenditure benchmark, which would affect the ACO's ability to share in Medicare savings.

The current MA quality program is financed through additional payments made to plans. There are only bonus payments and no payment reductions for poorer

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quality. In fee-for-service, there are both bonuses for better performance and penalties for poorer performance. The current MA program is not budget neutral within MA, nor is it budget neutral in relation to fee-for-service. Higher bonus payments in MA do not result in lower fee-for-service payments.

A question to consider in premium support discussions is to what extent bonus payments should be budget neutral and what is meant by budget neutrality.

When determining the extent of available bonus payments, an option in the alternative quality concept and premium support system is to have budget neutrality at the market area level -- that is, quality rewards would come out of the total fee-for-service (including ACOs) and plan spending in the market. Plans and ACOs with quality exceeding the fee-for-service reference would receive rewards, and those below the reference would have payment reduced.

I'll now turn it over to Carlos to discuss plan standards.

MR. ZARABOZO: We will now talk about a different but related topic, which is the more general issue of the

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standards that would apply to plans that wish to participate in a premium support system. Right now, private plans participate in the Medicare Advantage program, so in designing a premium support system, we have an existing administrative structure that can be the basis for determining plan standards. Presumably, the standards such as the requirement that plans be state-licensed would be retained in a premium support system.

MA has a variety of types of Medicare contracting private plans, but not all of the plan types may fit ideally in a premium support environment. We would expect HMOs and PPOs to be able to operate in the market areas for premium support, but regional PPOs, which currently bid on statewide or multi-state regions, would most likely have to function more like local plans.

There are also subcategories of specialized or limited enrollment plans that are not made available to all Medicare beneficiaries. For example, there are over three million beneficiaries in plans offered only to individuals with employer retiree coverage. The MA bids of such plans tend to be very close to, or at, MA benchmark levels. Consistent with one of the Commission's recommendations,

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CMS now treats these plans as non-bidding plans in MA. Their payments are determined by setting their bids at the prevailing bid-to-benchmark ratio for non-employer group plans. Under premium support, employer group plans could be treated in a similar manner.

In this slide we discuss auto-assignment of low-income individuals. The reason that this is an important matter to discuss is that states and the federal government currently pay the Part B premiums for a number of categories of dually eligible Medicare-Medicaid beneficiaries. Under premium support, the cost of the fee-for-service option could rise in relation to what it would have been in the absence of premium support, and the government subsidy would have to rise if that were the option where people would be auto-assigned. However, because there would be less expensive private plan options in such a case, the government could decide to limit its contribution to the premium amounts of less costly private plan options. In the same way that in Part D low-income beneficiaries are automatically assigned to qualifying low-cost plans, under premium support low-income beneficiaries could be assigned to low-cost options, but could choose to

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enroll in higher-cost options by paying a premium.

So Part D is one precedent we can look to for deciding how auto-assignment under premium support might work. Under Part D auto-assignment is based only on the relative bid of a stand-alone Part D drug plan. If the plan's premium is at or below the regional low-income benchmark, the plan can receive auto-assigned enrollees. Although Part D plans do receive star ratings that measure their quality, the star rating is not a factor in a plan's eligibility for auto-assignment.

By contrast, in the Medicare-Medicaid financial alignment demonstration for dually eligible beneficiaries, plan quality, broadly defined, has been a factor in determining whether a plan could receive auto-assigned enrollees. Plans that had low star ratings or were in a sanction status because of contract compliance issues could not receive auto-assigned or passive enrollment.

It is possible to consider both cost and quality when deciding how auto-assignment would work in a premium support system. We can use this slide to illustrate various approaches. The two circles on the right-hand side of the graph show two private plans with quality above that

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of ambient fee-for-service. However, only Plan 4, in the lower right corner, has a bid below the government contribution level. Thus, if one were to base auto-assignment decisions on both cost and quality considerations, Plan 4 would be the plan receiving auto-assigned enrollees.

However, there is a potential issue of concern, which is that Plan 4 may not have the capacity to accept all the auto-assigned enrollment. In such a case, one approach is to use the Part D approach, whereby only cost determines whether a plan receives auto-assigned enrollees, in which case Plan 2 would be eligible for auto-assigned enrollees in the lower left-hand corner.

Alternatively, if Plan 4 was at capacity and quality and cost were both considered, the next option for placing auto-assigned enrollees would be fee-for-service, with a bid that is lower than the bid of Plan 1 and, by definition, with quality equal to or exceeding the benchmark level of quality, which is fee-for-service quality.

Alternatively, treating quality as the primary consideration, one could say that the next plan for auto-

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assignment after Plan 4 should be Plan 1, in the upper right corner, which has higher quality than fee-for-service but which would cost more for the government to subsidize auto-assigned beneficiaries.

This concludes our presentation. In your discussion, we look forward to hearing your comments on the major issues we have raised on the subject of how to measure quality, how quality might be rewarded in a premium support system, whether there should be a budget neutrality component, and issues relating to auto-assignment and plan capacity.

Thank you.

DR. CROSSON: Thank you, Ledia and Carlos.

We are open for clarifying questions.

DR. HOADLEY: So I'm trying to -- with the different measures that you had on one of those early slides, I'm trying to remember the denominators or the bases we're looking at. So for MA, I think you said -- and that seems clear -- that all members of the MA plan -- and it's going to use the encounter data for that plan.

For the ACO, is it all attributed beneficiaries to that plan and then all of their care, regardless of

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whether it is within the ACO network or whether it's out of network?

MS. TABOR: That's currently how ACO quality is measured.

DR. HOADLEY: Okay. And then with fee-for-service, are we looking at all fee-for-service, or is it all non-ACO fee-for-service at that point?

MS. TABOR: So that would be up for discussion of what the quality benchmark would be, whether it's fee-for-service plus ACO or just fee-for-service populations.

DR. HOADLEY: Okay. And the market areas, if I read correctly in the appendix, the state boundary is one of the determinations. So in an area like this, you know, D.C. would be one market and the Maryland suburbs would be another. For the beneficiaries in fee-for-service, is it all of their care regardless -- based on where they live regardless of where the care is received? Is that what is generally done on that?

MS. TABOR: We would have to define that since fee-for-service quality is not currently measured at a population level. So we could define it either way, such as care provided within the local beneficiary's -- the

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local market area for any providers that are attributed to that market area, or based on the residence of the beneficiary.

DR. HOADLEY: And when we've done some of the data exercises on this, have we tried those different ways? And do we know how much that matters?

MS. TABOR: We have not, but we could.

MR. ZARABOZO: I would also mention -- excuse me -- that in MA, for example, if there were three market areas and it's private plans, a private plan in the District could use a hospital in Virginia or Maryland. So they have the same kind of issue.

DR. HOADLEY: So it would be [off microphone].

DR. CROSSON: Paul, on this point?

DR. GINSBURG: Yeah, I was just going to say pretty much all of the analysis of geographic variation in spending is done on the resident basis.

DR. CROSSON: Kathy.

MS. BUTO: Two questions. Particularly if one approach is to vary the government contribution based on some consideration of quality, but I think as well the auto-enrollment issue, how important is risk adjustment,

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and have we really thought about how that would be done? So that would be question one.

The second question is you mentioned -- and I looked in the paper as well -- the Medicare and Medicaid alignment demonstration, where quality was taken into account. Could you explain what quality measures they were looking at?

MR. ZARABOZO: In the case of the demonstration, there were plans that were below three stars that were going to become operating plans in the demonstration. They were not allowed to have passive enrollment. There was also a plan that even though it was a four or four and a half star plan, it was in a compliance status. There were contract management issues with that plan. That plan was also not allowed to pass enrollment. So it's using the current available information about -- yeah.

Now, your first question, risk adjustment, do you mean -- we have risk adjustment and payment, right? Is that your question, or risk adjustment and the measures, which gets to the --

MS. BUTO: If we're going to be comparing things like preventable hospitalizations, et cetera --

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MR. ZARABOZO: Right. And a lot of those measures are risk-adjusted.

MS. BUTO: Okay. So the measures themselves are risk-adjusted.

MR. ZARABOZO: Right.

MS. TABOR: They're currently adjusted for patient characteristics such as age, comorbidities, patient frailty, and then as far as the healthy days at home, we have been --

MS. BUTO: Right.

MS. TABOR: -- modeling risk adjustment, and we will be presenting those next month.

MS. BUTO: Okay. Because I would think that if we're going to compare across these different approaches that it would be important to have that nailed down. Otherwise, there's a huge possibility we'd be disadvantaging, especially if we bury the government contribution, so thank you.

DR. CROSSON: Alice.

DR. COOMBS: So I heard with interest the paper. One of the things that came across my mind was the whole intersection of MACRA and the MIPS in terms of being able

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to project going forward. So I was wondering if you guys actually thought about some of the intersection of what would happen in a MIPS environment with a fee-for-service and how you would establish the benchmarks.

MS. TABOR: So I don't think we thought exactly about MIPS, but I think we made the assumption based on a 2014 report that quality programs that are in place for providers, such as MIPS, which was formerly the value modifier and the physician quality reporting system, would continue.

DR. COOMBS: So there is a part of MIPS, which is you're talking about, a resource utilization. There's some areas of MIPS now that are totally different than just a PQRS program. So I'm just wondering going forward how those other pieces of the quality benchmark or the circle would be inculcated in a picture like this.

MS. TABOR: So we could continue to have fee-for-service provider-level quality programs continue outside of this premium support and alternative quality model, or perhaps we could consider some of these provider-level measures as part of the alternative quality model. So that would be a question for the Commission.

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DR. MILLER: Yeah. And just to -- and I am not going to say anything that's different or inconsistent with that, I don't think. You know, a lot of what we're headed towards here is a chapter in June that kind of goes through high-level design issues, and so exactly all the MIPS interactions and everything. Just to be very direct, for the purposes of this paper, we haven't thought that through yet.

And I think the way that deck kind of breaks out -- and some of this has come up in previous conversations -- fee-for-service in these kinds of models is always kind of this difficult, you know, area to treat because you could leave individual MIPS, readmission penalties, that type of stuff running in fee-for-service, but what then you'll also have to always be thinking about is is that creating odd cross-incentives when everybody else is being judged on a different set of measures. And so that's one problem.

I'm just going to say some things out loud because this is just conceptual conversation. You could say, "Okay. I'm going to get rid of all that, and I'm going to put fee-for-service on that same list of measures

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that she had up there and just say you're eligible" -- this is one extreme position -- "You're eligible for bonuses if you're in an ACO or an MA but not necessarily in fee-for-service," or you could say, "You could be eligible in fee-for-service, but the real problem" -- and this is something that has come up in your conversations before is if you wanted to reward in fee-for-service, what's the unit? Because the unit then is just the geographic territory of a bunch of people, a bunch of providers.

And then you could say, "All right. Some people have said things like this: I am going to create kind of virtual referral areas within fee-for-service." And I think we're going to talk about some of this in a subsequent upcoming conversation, where you might say, "Okay. I'm going to impose some kind of a virtual group even in fee-for-service and reward on the basis of these measures with the point being if you, Mr. and Mrs. Provider, don't like who you've been organized with, then think about an ACO or think about a managed care strategy.

And so that whole deck of decisions is kind of embedded in this "What do you want to do with fee-for-service?" But the short answer is we haven't cranked

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through a lot of that MIPS stuff, and I think that's some of what we are going to need to talk about here.

Sorry, Ledia. I didn't mean to get in the way.

DR. CROSSON: Rita.

DR. REDBERG: Thanks for an excellent chapter.

My question -- I have two questions, I think. One was in the mailing materials on page 17. We were talking about low-performance indicators and that a number of plans have been in that status. I was just wondering if you could give us an idea of how many beneficiaries are in plans that have low-performance status currently.

MR. ZARABOZO: Actually, Andy may have that number.

DR. JOHNSON: No.

MR. ZARABOZO: No. Okay.

DR. REDBERG: Get back to me on that one?

MR. ZARABOZO: Yes, we will get back to you on that one.

DR. REDBERG: And the other was, again, I really like the idea of reducing the number of quality measures and going towards outcomes and not process because I think it is very burdensome and a very unclear benefit to have a

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lot of process measures. But for healthy days at home, when it says "no interactions with the health care system," I'm just -- and maybe we're still going to get to this -- does that mean if you had a visiting nurse day, that would not be a healthy day? If you had an outpatient doctor's appointment, would that be a healthy day? How would we do all that?

MS. TABOR: So we'll be discussing in more detail next month, but I can let you know that the measures currently defined as you have 365 days a year, if you had an inpatient visit, post-acute care visit, home health visit, ED visit, then those would not be healthy days at home. But if you had a visit with your primary care doctor, that's considered a healthy day.

DR. REDBERG: Thank you.

DR. CROSSON: Pat.

MS. WANG: Can you say more about the definition of a local market? I read the appendix. I didn't really quite understand what a local market -- how big that was.

I mean, I know you had the concept of sort of evaluating hospital areas. I forget what you called them. What about the situation of MA plans that may be

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concentrated in sort of underserved, rural, or urban areas within that large market? I mean, how are you thinking about that?

MS. TABOR: I can start off.

So defining the local market area -- so there's about 1,200 local market areas in the nation. So we've taken core-based statistical areas, which are generally metropolitan areas, and then taken any of those metropolitan areas that are across state lines and divided those up, so the D.C. area is a perfect example of that. The D.C. area is one entire core-based statistical metropolitan area, but we divided up into Northern Virginia, D.C., and then the Maryland suburbs, so that's three local market areas.

And then, within those local market areas, there are hospital service areas, and there's about 3,000 hospital service areas.

So I'll give a local example of that. In Northern Virginia, which is one local market area, as we define it, there are about 11 different hospital service areas that are generally defined around major hospitals, so Fairfax, Arlington, Falls Church are different hospital

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service areas.

DR. MILLER: But for purposes of this conversation so far, the hospital -- like when you put the picture up, the hospital service area doesn't really enter into it. In this exchange between you two, D.C. would be the three markets that she spoke about.

I think the HSA is kind of a distraction. No, no. But it could come up in the exchange where if you start talking about what do you want to do about fee-for-service, should it be one block market or do you want to divided it up, that's where the HSA probably becomes part of the conversation, if you want to go in that direction.

MR. ZARABOZO: But the question on the rural area, what we're looking at is metropolitan areas, micropolitan areas, and then you have other areas that are neither of those. So the rural areas, you have non-micropolitan, non-metropolitan areas, and those are grouped into what are also known as HSAs, health service areas, different terminology, that were developed by the National Center for Health Statistics.

So you have like one way of doing it. State, for example, is I will take the metro areas and the micro

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areas, and then the rest of the State is just the rest of the State. This says, no, the rest of the State can be divided up into geographic areas based on the patterns of care that people receive. So those are the areas.

DR. MILLER: So you have two HSA running around --

MR. ZARABOZO: Yeah, yeah.

DR. MILLER: -- here, one in the rural areas and then one is the hospital service areas, which are a bit of a different animal.

MS. WANG: I just want to ask a clarifying question on the sort of concept of auto-assignment for duals. Are you assuming that auto-assignment would be if an MA plan were the low-cost, high-quality option that they would have to be a dual SNP, or are you thinking duals would auto-assigned to regular MA plans?

MR. ZARABOZO: Well, for one thing, we raised auto-assignment as something that might happen. That's a decision that needs to be made. But we did not go -- we did not consider that question of whether or not it had to be a D-SNP and whether or not there would be D-SNPs continuing in a premium support environment. That's

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another -- that's one of those specialized plans. We used employer groups as an example. D-SNPs is another example of specialized plans, would they or would they not continue in a premium support environment.

DR. CROSSON: Pat, do you have a point of view on that or just asking?

MS. WANG: I mean, D-SNPs, for better or for worse, are required by CMS to meet different requirements around model of care that are supposedly more oriented towards low-income beneficiaries. So it goes to, I think, the point you were making about sort of what do you do with regulatory compliance and how do you fit that in.

I mean, currently, CMS kind of likes duals to be going to D-SNPs because it's more specialized to the population. So, you know, I happen to agree with that perspective, but I think it's something to consider, because if the only -- if the low-cost, high-quality option, for example, in an area is, you know, like a PPS-type plan that really sort of specializes in a different population, is that the optimal place? I mean, I don't know, especially if you're talking about auto-assignment.

DR. MILLER: I also want to ask this. Maybe we

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can surprise Andrew with another question.
[Laughter.]
DR. MILLER: But of the people who are in MA, the proportion of the duals who are in MA, the proportion that are in D-SNPs versus regular plans, didn't we kind of have this conversation?
MR. ZARABOZO: Yeah. I think, I mean, the last number was--like on the full duals, I think 60 percent were in D-SNPs or some larger number were in D-SNPs.
And I'll give Andy an opportunity to go to the bathroom before we ask him any questions. So, Andy, did you need to go to the bathroom? Okay.
[Laughter.]
DR. MILLER: It's generally not how we do things, Carl.
[Laughter.]
DR. MILLER: The only thing -- point I wanted to make in that exchange is there is a fair block that are in.
DR. CROSSON: Bill and Craig, on this point or just in line?
DR. SAMITT: In line. Just in line.
DR. CROSSON: Okay. So Jon is next.

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DR. CHRISTIANSON: I was just going to also ask some questions about the healthy days at home measure, but it sounds like we're going to have another deeper session on that measure, so maybe I should just wait on those questions.
MS. TABOR: It's up to you, but, yeah, next month, we're planning to present a detailed update on the measure.
DR. CHRISTIANSON: It makes sense for me to wait till next month.
MS. TABOR: Okay.
DR. CROSSON: Craig.
DR. SAMITT: I also had a question about auto-assignment. I'm curious about the frequency of auto-assignment and passive enrollment, also about the frequency of capacity constraints at the plan level. We talked about that as an issue we need to work through, but I'd be interested in knowing how often this actually occurs.
MR. ZARABOZO: When I used to work at CMS years ago, there were certain plans. The group or staff model plans were plans that would have the capacity issues. I'm not sure how common it is now to have a capacity issue.

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Now, also, another consideration of capacity can be financial considerations, that too large an enrollment and so on, so --
DR. SAMITT: And frequency of passive enrollment?
MR. ZARABOZO: Passive enrollment occurs in the financial alignment demonstration.
There is seamless enrollment under Medicare Advantage, where a person who is currently in a plan, in a commercial plan, let's say -- let's say Anthem, for example. If the company has a Medicare Advantage plan, they can enroll that person passively into the Medicare Advantage plan, inform them they are being enrolled. They have the opportunity to opt out.
We don't know the frequency of that. In fact, there was recent press coverage of that issue, so CMS is, I think, looking to provide more information about the frequency of that occurring in Medicare Advantage.
DR. CROSSON: Bill Hall.
DR. HALL: Could we put Slide 12 up again, the 2x2 table?
So 2x2 tables are really very useful in a qualitative sense, but they tend to fall down on the

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quantitative side; for example, horizontal access, range of level of quality. That includes all the new measures that we talked about here, but there's a big difference between low quality based on low-value care and mortality in the hospital. They're just totally -- they're not equate-able.
So I thought I heard you say that there would be situations on auto-assignment where we would accept lower quality if the price was right. If I were a critic in looking at this 2x2 table, I'd say, "Wow! That's a new concept."
MR. ZARABOZO: Again, these are illustrative examples.
DR. HALL: Right. I understand that. I understand that. That's what my preface was.
MR. ZARABOZO: So the only point there was we have a couple of current precedents for how auto-assignment would work, and the precedent under Part D is below that line, which is it's just cost. So, if you wanted in premium support to say it's just cost, quality, because we are paying the dollars, we the Federal and State government, you could say all plans have at least a minimum acceptable level of quality. You would want to threshold

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the quality. But, anyway, it's a decision to be made. It's part of the design of premium support, who will get auto-assignment.

DR. HALL: Okay.

DR. SAMITT: Just to clarify, auto-assignment today is not below the line. It's on the dotted line, right? So auto-assignment is to fee-for-service, not to plan?

MR. ZARABOZO: Right. Today, there is only auto-assignment to fee-for-service.

DR. SAMITT: Fee-for-service.

MR. ZARABOZO: Yeah. That's --

DR. SAMITT: Right. So it's not below.

DR. CROSSON: Jack.

DR. HOADLEY: On this point, I mean, the one thing I would note is in the Part D world, while you write that quality is not taken into consideration, sanctions are. So if a plan is under sanction, they do not receive the auto-assigned enrollees, but if the plan simply is a low-performing plan with two stars, they would get the same share of auto-enrollment as any plan at any other quality level under current rules.

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DR. CROSSON: Sue.

MS. THOMPSON: In the reading materials on page 9, patient experience measures, and you referenced that there would be an increasing cost to the program to get all this alignment done. Can we talk a little bit about patient experience measures and how much have we looked at correlation between the subjective outcome of a patient's perception and a lot of these other measures? And is there correlation to the outcome measure? I'm just curious. Have we spent any time on relooking at how that all fits together and does not predict the other?

MS. TABOR: So, as far as patient experience relating to other outcomes, generally providers that do have high patient experience outcomes do have -- do well in other measures, in other clinical quality measures, so there is a correlation there. We can get you more specific data on that, but that is kind of a general known fact.

There's also been some data to look at when we're talking about the validity of the CAHPS survey. There is a recent Health Affairs article that looked at Yelp reviews of hospitals and looked through for keywords of how people define quality within the Yelp review and compared it to

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the CAHPS survey, and there was a very high relationship between how people wrote about quality and the types of questions that are asked on CAHPS surveys.

We've also looked at fee-for-service caps versus MA caps, and there are some differences between performance across the different market areas. So I think that provides some inspiration for being able to compare across the market areas using CAHPS.

DR. CROSSON: Rita.

DR. REDBERG: Just on that point, I think in Tab A, near the end was that Health Affairs summary that suggested that there was some correlation between what people write on Yelp and HCAHPS, although we published a paper a few years in Archives of Internal Medicine that suggested patient satisfaction was actually inverse correlated with mortality, obviously, just an association, but it's a very interesting and unresolved question. I think it's hard for patients to really make assessments, I think, on what they are satisfied with and the actual quality of their care in terms of was it appropriate.

DR. CHRISTIANSON: I think the one issue there is why would we expect them to be correlated.

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DR. CROSSON: Okay. Seeing no more questions, could we throw up Slide 13 again?

So here are some of the options, I think, that the staff has asked us to comment on, so we'd like to hear preferences to the extent that people have them. And David is going to start the discussion.

DR. NERENZ: Thanks. I would like to focus mainly just on the issue of the quality measures and less so how they're used in the program because, clearly, the quality measures are the foundation upon which the rest of this is built. So I'd like to talk about that, and I didn't realize, as I was thinking about this in advance, that you were going to come back next month. So, actually, what I'm going to say, I think, tease out the sort of questions that we can discuss and perhaps you can bring forward in more detail. So that's the spirit of this.

I'm going to do a very strange thing, and I didn't know if I should do it, but it may be the last time I ever do it.

[Laughter.]

DR. NERENZ: I'm going to use just a little visual image to make a point, and I understand this doesn't

work on the transcript, but I promise it's not detailed, it's very generic. I will use words for people who can't see this.

[Laughter.]

DR. CROSSON: Get on with it.

DR. NERENZ: I want people just to have in mind a very generic cause diagram, a box and arrow diagram of causes of something. And all I've got in it, all I need to know, is that there are many causes and there's one outcome. I just want people to have that image in mind. I'm going to use it a little bit, and it won't take long. And, you know, it's a classic thing. You've all seen it. It's used in path analysis. It's used -- okay. Lots of causes, causes move left to right.

The one thing about this is that the measures we're talking about here -- and I think we've said this before -- they're multiply determined. They're not just the result of one thing. They're the result of many things. And so that's what we need to walk through.

So then what I want to go through is where's quality in this. Where's quality and what do we measure? Sort of like, "Where's Waldo?" You know, where's quality?

Okay. Well, one way to do it -- and I've just drawn a big circle around the whole thing. That's a big circle around the whole thing. So the whole thing is quality. We could do that. And this is kind of a Donabedian sort of thing to do because you say, well, the structure and the process things are over in this causal network, the outcome's on the right-hand side, and anything we measure, it's quality.

Now, in this context that we're talking about here, I think that causes a few problems because it doesn't make us think sharply about filling in the blank of quality of what. We've talked about quality of care, but what does that mean? You know, do plans do care? Well, no, not really. So I think when we just throw the quality label around the whole thing, we don't think sharply enough about exactly what it is that we think we're measuring, including when we measure the outcome. Okay?

All right. So you can draw the circle a little more narrowly, and all I've done, for purposes of the transcript -- and everybody else -- is now I've left the outcome out of the circle. So quality is over in the causal part, but it's not in the outcome. Now, why would

you do that? Well, what it does is it sort of emphasizes the point that the outcome is a result of quality, it is the effect of quality, but it is not sort of quality itself. And it just reminds us that when we measure these outcomes, we're measuring a property of a person or a group of people. But when we use the measure, we're shifting the reference. Now we're talking about the property of a plan or a property of an ACO. So it's just a visual way of thinking. We can think about this a little differently, and I think in some ways we have to.

All right. Last one, I promise. This is actually how I prefer to think about it, and I think it reflects the reality we're in. What I've done now is I've drawn the quality circle much more narrowly. I've only picked up 2 of 20 causal factors. And I said, now, that's quality.

Now, why would I do that? Well, think about the measures and think about environment. The measures we're talking about here -- let's take Healthy Days at Home. That reflects in a Medicare population health care, but it picks up 64-plus years of diet, exercise, smoking, drinking, occupational exposure, environmental exposure,

previous health care, lack of previous health care. Okay. So the point is that then a whole bunch of this causal network in this way of thinking is not quality. It's something else.

Okay. So what does that mean? It means now we've got a big signal-to-noise issue because we're measuring the outcome. But there's a quality signal in here that we're trying to detect, but there's a whole bunch of noise. Okay, so -- and the noise has two subparts. There's random noise, kind of white static, just random variation, that doesn't bother us too much most of the time, and we attack that with sample size. We can live with that. But worse than that is bias, that there's some elements of this other stuff that produces movement in our signal. It pushes a number up or it pushes it down and we get it wrong. And there we have to do, as Kathy -- risk adjustment.

Now, again, this is nothing new, but I'm just pointing out the intensity of it. And it raises the question that I want us to be looking at in all these measures: What is the signal-to-noise ratio? I think that should be expressed in a quantitative fashion. We almost

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never ask that about quality measures that we use.
Now, in some other domains of measurement, we do know something about this, and it's very sobering, that the -- and we talk about it as weak correlations between process and outcome. But if you just think about it in a signal-to-noise framework, when we measure the outcome, only maybe 5 percent of the variance in the outcome maybe influenced by the signal that we're after. It really can be that weak. And all this other stuff is floating around in there.
So I'm sort of using this to sort of emphasize that we have to take the issue of risk adjustment so seriously when we're focusing on outcomes, not so much about process but in doing outcomes.
And even our language -- you know, we talk about these things as measures of quality. Well, that to me makes sense if, you know, something like 70 percent or so of the variance in the outcome is explained by the quality things we're after. Then I can say, okay, that's a measure of quality. But as soon as that r-squared starts to drop down, then I think the word "measure" begins not to be quite right. But we keep using it, and we get trapped in

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our language, and we take it too seriously. Yet down the middle, I think maybe we should talk about indicators of quality, not so much measures. And we go way down into the low variance explanation, and I think other words are -- we should talk about hints of quality or glimmers or omens or portents or something. So no more diagrams.
Okay. So I think that gets us to five questions that I would like, when we talk about this stuff, we should keep in mind and, actually, if we're coming back next month. One is, I think, for each measure I would actually like to see this diagram laid out with labels. Now, I don't think that's a crazy thing because quality improvement teams do this all the time when they make fishbone diagrams, and that's kind of the same idea. Don't have to do 10 years of research. I just think we should have in front of us what does the causal diagram look like.
Then the second question, where do you draw the quality circle? And that's a debatable thing, and I'm not sure we'd all agree on it, but I think it could be a discussion. What elements of the things that we know cause belong in the concept of quality, and then whose property is that?

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Now, the third question is: What set of factors do we want to hold the plans or ACOs accountable for? Now, you can frown and say, wait a minute, the second and third questions are the same question. But they're not really. And, in fact, the distinction is part of what fees this SES adjustment debate, that we could say as a matter of policy that plans or ACOs should be formally accountable for things that are not strictly quality of care -- social determinants of health, poverty. We could just say that because we hold plans accountable, we do not adjust for these factors. Or we could say the circle of accountability is the same as the narrowly defined quality, and then we adjust for everything else. So that's -- we see that.
Fourth question: What is the signal-to-noise ratio? I think for some of these things that is a quantitative thing I'd really like to see. If we measure the end result, how much of the variance in that is explained by the things we have defined as quality back in the network.
And then last question: Then what's the risk adjustment model? And I know you said in some of these

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cases it's percolating and it's there, and that's good. But I'd like to see the variables, I'd like to see the coefficients. And then sort of what happens to the signal-to-noise ratio when you adjust?
So these are things I'd like us to think about, and I went through this whole song and dance because I think when we talk about quality measures, even outside this context, we usually are not demanding enough about these properties, and we say, okay, this is part of quality so let's measure it. But we end up doing a whole lot of measurement in things that aren't all that information.
Thank you.
DR. CROSSON: So, David, I just want to poke a little bit, because I think you've brought up a very important point that, you know, kind of reflects the transition that's been going on in the Commission around quality measurement for a few years, which is -- and I'm going to oversimplify, but fundamentally sounds something like this: A lot of quality measurement has been based on process measures, and to some extent, the reason for that is that they're easier to conceive of, in many cases easier to collect, the time frame for their development is

generally shorter than for outcome measurements. But there are problems. To the extent that one is -- and I won't list all of them, but to the extent that one is using process measures, you can end up with the providers directing all their attention to those specific process measures as opposed to other aspects of care which may be more important. You know, what is important is not necessarily measurable. And so we've had, you know, kind of a philosophical bent that, to the extent that it is possible, we would like to see a transition to outcome measures, broadly defined, I think. And, you know, that then brings in a whole range of issues that you describe, which, you know, is roughly along the lines of if we're going to do outcome measures, how adequate is risk adjustment and how broadly defined should we be considering risk adjustment? And are there areas of outcome measurements that are so contaminated, you know, by confounding variables that they're just simply not appropriate for this purpose?

So I wanted just to see, are you thinking that we should be more temperate in the evolution of this notion or that -- and I think what you're saying is that you'd like

to see a good deal more analysis and detail around the issues you described before we latch onto particular outcome measures? Is that a fair summary?

DR. NERENZ: No, that's absolutely right, and I am a fan of this general direction. I like this direction, I think. But when we go in the direction of using outcome measures, I just think we inherit a set of conceptual and technical problems that we need then to step up to. So I just would like -- that was really the fundamental point, that as we carry this forward, say into discussion next month, or if this makes its way into a June report -- and I understand from her comment this is still a general broad-brush thing. But if we're taking these measures seriously -- and I am -- then I think we want to work these things through, so that if we actually build a system on this foundation of measures, it works, that the measures are valid and they are not biased and they actually represent meaningful dimensions of quality that sort of are properties of the entities we're comparing, but also are things that are valued by the consumer.

Again, I favor this general direction. I just wanted to lay out as clearly as I could some of the

challenges that I think we inherit when we go there.

DR. CROSSON: I think on another point, we could probably -- don't you think we could save money by not having these things?

DR. MILLER: I couldn't even see his pictures.

[Laughter.]

DR. MILLER: It can't be on yellow paper.

DR. CROSSON: Okay. So now we're open for commentary, focused on David's point, if you wish, but also on what's on the slide there? I have Jon and Paul so far -- all right. We're going to have a lot, so let's take Jon and Paul -- let's take Jon and then move this way.

DR. CHRISTIANSON: Yeah, so one of the arguments against process-oriented measures, as you all know, and we've repeated, is that some of them are not very well -- we don't think they're very well correlated with outcomes. We wish they were, but they weren't.

But what about process measures that are? I mean, they have advantages, because then these are things that you would expect a physician, to use an example, to do in their office irrespective of the socioeconomic characteristics of their patient. So you kind of avoid

some of this quagmire of how to adjust for socioeconomic characteristics if you can find process measures that we know are very highly correlated with outcomes. You still have other issues with process measures, as Jay was pointing out, but at least in that -- so is it that we're sort of all in and everything has to be an outcome measure? Or can it be a mix where we identify areas where process measures are the best way to go and some areas where outcomes measures are the best way to go?

DR. NERENZ: I think that's a fair statement, and the reason we have a lot of process measures in it is they may be highly correlated, although I think we should be explicit about what "highly" means. You know, a correlation of 0.10 doesn't -- that often stands in this domain for highly correlated. Actually, that's a problem. But I think in this discussion context, we have the issue of are plans and ACOs the entity that are really responsible for process. Now, maybe yes, maybe no. We have gone pretty far down that path already in terms of measures that exist, but we're sort of straying away from that path here. And then is there actual meaningful variability at the plan or ACO level on defined process

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measures?
So the portfolio of measures in this program could eventually include some process, but I would say, I would stipulate, they want to be highly correlated, more than 0.10, and we want to be comfortable conceptually that plans and ACOs are directly responsible for those measures as opposed to just a mathematical collecting point.
MS. WANG: I think this is a really important conversation, and I'm glad that we're going to keep having it because obviously there are many, many measures of quality, and it's additive. Nothing seems to come off the list very easily. And since the stakes are becoming higher and higher, whether it's setting ACO benchmarks or plan levels of payment or, you know, conceptualizing that premium support could actually influence, it's very consequential. So I think it's important for us to continue to talk about these.
You know, I do observe that many of the process measures that -- or the measurement of quality that existed four or five years ago has shifted from process to outcomes. It has. And while outcomes is the ultimate desirable, the stakes are also higher because, David, to

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your point, evidence-based process measures are evidence-based, but the outcome -- Health Days at Home is an outcome. That's a big concept that has -- you know, your diagram probably -- you could multiply the number of little circles that were on it. So as we urge moving in the direction of ours, I think that we have to be mindful that what we're endorsing is the real deal and we're really comfortable with it.
I want to make a statement just in general about patient satisfaction and CAHPS. I think that CAHPS is very important for people to know. I think it's important to -- a Yelp review is -- you know, it's like, well, this is the buzz around this provider or this whatever. That's fine. I personally feel like we should be very cautious about saying the Yelp review is now going into the assessment of quality for that ACO, because the correlation -- I believe that consumers assume that the health care delivery system they are selecting is high quality, and that is sort of the current focus on, well, how do people -- you know, how satisfied are they, how do they rate this stuff is confounding when it is overweighted as to what -- you know, even though quality measurement is somewhat imperfect, it's

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confounding the overall assessment. I mean, in theory, you could weight CAHPS to such a degree because it seems to be moving in that direction that the actual clinical quality scores of a provider are through the roof, but people are not satisfied for whatever reason. It's a Yelp review kind of thing, and the quality overall gets blended together and presented as something that's mediocre. So I just want to state that.
I have some concerns -- I don't really understand some of the -- we didn't really get to talk too much about budget neutrality. I think that one of the concerns that I would raise there in the concept of budget neutrality within a market area is that, you know, you could go to Bill's home area, 75 percent five-star MA plans and say that's budget neutral. You could go to where Sue is where there are no MA plans, there's a great ACO, but it might be in a state of evolution. Are you locking in funding and not giving, you know, the system an opportunity to, you know, rise if you're just recirculating the existing dollars that are locked into a baseline up and down among the various entities there.
I really appreciate the discussion about

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socioeconomic status adjustment, risk adjustment as it exists. You know, there are certain demographic factors in a lot of risk adjustment measures, but socioeconomic status is really not present in, you know, preventable admission, readmissions, and other key measures that people are focused on. So I think it's very difficult but very important to continue to sort of push at that.
And the final thing that I would ask is at some point -- and maybe this is planned by the staff -- to actually test the completeness of encounter data, because if the idea is that, you know, we'll model this stuff and eventually base this on encounter data, it's kind of new. I don't really know if we have an assessment. So I'd be very interested in your assessment.
DR. CROSSON: Pat, just let me ask you one question. With respect to -- without trying to adjudicate CAHPS as a measure of whether it's a good one or not, you know, sort of the classical thinking in quality measurement is that the experience of care in some cases -- and the best example probably is labor and delivery, you know, where the outcomes, generally speaking, are good are rather consistent, that the experience of care, in this case for

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the mother or perhaps for the baby, is in some ways as important as anything else. So I don't think you were saying, you know, eliminate the experience of care as part of the consideration here. Is that right?

MS. WANG: I think the experience of care is very important, but I think that the current composition of CAHPS, I think that we just need to be cautious. It's more a matter of how it's integrated into an overall quality score. It's another confounding circle on his chart. I think it's incredibly important. I think it's important for people to know.

So if you're an MA plan that focuses on low-income people who live predominantly in health profession shortage areas, they're probably going to rate kind of low their ability to get a doctor's appointment in the time that they want. It is also equally possible that those doctors provide excellent care; there just aren't enough of them. And, you know, when those assessments of like I couldn't get an appointment because the only doctors who are in the area are in clinics or FQHCs or scattered and there's a shortage, that's why it's a HPSA, when that kind of gets integrated into, okay, it's a poor-quality plan

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overall and it has the consequence of, you know, lower premium support -- you know, I just think it's a question. I think -- whether that's the outcome that you want.

I mean, one possibility is -- I mean, I think it's important for transparency around those things. The Yelp review, how are people -- what's the buzz? How are people feeling about this? There's definitely a relationship. So it's either a matter of weighting in the total score, which I would favor less rather than more, and transparency and display, because there's definitely a relationship. But to the points that were raised, I'm not really sure whether it's been demonstrated scientifically or empirically that it really is correlated to clinical quality.

DR. CROSSON: Thank you.

DR. REDBERG: Jay, just a question on CAHPS --

DR. CROSSON: On that?

DR. REDBERG: Do you know what percentage of patients fill them out? Because I guess my concern is I think it's very low, and it's a very biased sample.

DR. CROSSON: Bill, do you want to comment on CAHPS?

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DR. HALL: Usually, CAHPS scores are accumulated after the patient is discharged from the hospital, and it's often in many cases filled out by not the patient but by someone who is a caregiver, Medicare. So it's probably less than 50 percent of the time the actual patient affected fills this out.

The other thing -- I'll wait. I'll have a little more to say about CAHPS later, but that's an answer to your question.

DR. CROSSON: Okay. I want to redirect attention to the slide. I mean, these are all good comments, but we want to try to advance this. So there are some options and thoughts up here as about which direction to go.

DR. GINSBURG: Sure. Two things I want to talk about. First, the presentation asked for feedback on measuring low-value care, and I want to say that I'm enthusiastic about pursuing that. But I think we should think of it as transparency -- what the audience is for this transparency, and I think the best audience, at least initially, for this type of transparency would be policymakers and other influentials. And I'm somewhat inspired by this because of the experience with price

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transparency around the country where it's often been very unsuccessful as far as people don't use the information. I think the greatest examples of success have been initiatives focused on policymakers and influentials, and the one I really have in mind is the Attorney General of Massachusetts' publication of hospital payment rates, those negotiated with health plans, which, from what I could tell, has had a profound effect on policy and behavior by employers in Massachusetts.

So I think those are the lines we should think along. It's also safer to do that, because to the degree that what we've indicated we have chosen are controversial, it just fosters the discussion in the policy world. So I think that's worth pursuing.

I want to raise a somewhat devil's advocate, somewhat not, question about everything I've seen in the paper and our discussion has assumed that we should be paying more for higher-quality care. And I just want to question what that means. In a sense, what we're saying is that beneficiaries on their own are not going to choose higher-quality providers and it would have been better for them if they did, and we know better through our measures,

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as flawed as they are, which providers they should be seeing, which Medicare Advantage plans they should be choosing. I think we have to have some more humility in that and be very explicit about what it means to actually be giving quality bonuses and penalties to plans or providers, you know, based on how we measure it.

In the plan area, of course, much of our experience is with star ratings in Medicare Advantage plans. I think they came about because of a concern about wanting to encourage more plans to get into the MA space as, you know, a non-budget-neutral add-on, and also because of concerns about quality. And the star ratings I think have really dramatically improved the star ratings that plans get. You know, how much better the beneficiaries are from that, I'm not sure. They've probably outlived their usefulness as bonuses, at least on a non-budget-neutral basis.

So the real question is whether quality information should be used as information for beneficiaries to help them make decisions as opposed to taking over from them and saying, well, you know, you don't understand this, you'll never use it, we really think you should be in

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better quality environments, we will give bonuses and give the plans and the providers a discount to push you into them.

So it's this, what I mentioned, a devil's advocate question. I definitely think we should be budget neutral if we are going to pay more for quality. I think we should be paying less for lower quality. I think we'll probably be less aggressive if we're being budget neutral because of all the concerns about the shortcomings of our ability to measure quality.

DR. CROSSON: Thank you.

MS. THOMPSON: Applaud the discussion and look forward to upcoming discussions. Agree we need to at best be budget neutral. And also in structuring the fee-for-service as a reference for reward question mark, MA and ACOs only rewarded, as we structure these ideas around rewarding quality, keeping in mind we need to be rewarding these new -- these payment models that will drive towards reductions in utilization and not continuing to feed fee-for-service. So that's just a high-level comment. But I love the conversation and look forward to continuing.

DR. CROSSON: Thank you.

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DR. SAMITT: Great chapter. Thank you very much. You know, I fully endorse actually all that's been discussed, and I know we can get into a very academic argument about how to measure quality and what's included in quality and which are the right outcomes measures. But I kind of want to go back to the purpose of all of this, which is the concern that in a premium support environment, if all we share with consumers is comparison over cost, then I think we definitely do a disservice. And I think the reason we do a disservice is something that someone made that beneficiaries assume quality is equal in the health care environment, I believe, for the most part. And I think the reality is we know that's not true. When we look at the measures that are being proposed for outcome measures, preventable admissions, mortality rates, Healthy Days at Home, we will see great variation in performance from plan to plan. And, frankly, I think that consumers should know that there are differences in quality and that we should help beneficiaries choose for value, not just choose for cost. So I couldn't endorse enough the recommendations that are put forth here.

I do want to make a comment. The budget

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neutrality, I agree with Paul, you know, it feels that since the decisions that beneficiaries will make are going to be at a market level and in essence it's going to be you're either going to choose high value or low value, it feels that budget neutrality will be crucial because that is the driver of the local based decision by the beneficiary.

In terms of consumer satisfaction, customer satisfaction, this is a real tough one for me because I am a real advocate for measuring patient satisfaction, although there's a perception element to this, and what I'm afraid of is an environment -- it all depends on how much we weight customer satisfaction and the quality measure. What I'd be afraid of is that we would guide beneficiaries to a plan that has tremendous patient satisfaction scores or CAHPS scores but terrible quality outcomes and that it could water down the necessary sharing of information with beneficiaries about true quality. So I think it should be counted. I just think it should be counted as a minority and as a variable that consumers get to see, but isn't something that actually can disguise true quality of a plan.

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And then, finally, auto-enrollment, I think we need to auto-enroll over quality as well, with the reality being that if MA plans are of higher value than fee-for-service, that beneficiaries are auto-enrolled into those plans as opposed to into fee-for-service. And I haven't thought more about what happens in capacity constraints, you know, beyond the right lower quadrant, as you described, who goes next. Is it the right upper? Is it fee-for-service? Is it the left lower? I would hope that we wouldn't guide people toward low cost, low quality. So, you know, I think we need to think more about that, but I do believe in the concept of auto-enrollment overall.

DR. CROSSON: Thank you.

DR. HALL: Thank you, Craig, for those comments. I want to just say a word about auto-assignment, I guess. Since I've been on the Commission, we've made tremendous strides in terms of how we are measuring outcomes of health care, and particularly in older populations, the idea of functional state, frailty states, what can they actually do in the real world, these are incredibly important concepts, and I think we've done ourselves proud, particularly over the last four years there. And this is in the same vein

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today.

What's bothering me a little bit is that the other major principle that I've been taught in this Commission is that we honor patient choice, that this is an important concept of Medicare. Obviously, there are situations where that has to be modified, and LIS is the one I would like to mention.

We can have a system where we say an educated population can have that choice, can understand the differences and the nuances of quality, and can make informed decisions that are right for them. I think that's there. But once we take the responsibility for making these decisions, I think we have an incredibly responsibility to do what I think Craig was talking about, is to make sure that that quality things -- it's not just one integer, either it's quality care or it's not. And so it really falls on our shoulders because we're kind of the shepherds of that population.

So that's why when I saw the two-by-two table, I said in an oversimplified viewpoint, it looks very much like that low price trumps quality. I know none of us really believe that inherently, but I think we have to keep

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that foremost in our minds as we make some of these decisions.

But this is really great stuff we're doing in this area.

MS. BUTO: So I was thinking about this in a similar way to the way Paul was thinking about it, but I have to say, first of all, Dave, I think you've raised the bar on Commissioner opening statements, and I'm trying to think of what cartoon I could bring --

DR. NERENZ: Either that, or it's into the quicksand. It's probably more the latter.

MS. BUTO: No, I thought that was really amazing. And where I was coming at was slightly different than Paul's, which is it's always bothered me -- and I mentioned this to Carlos before we started -- that we don't have a basic standard of quality built into all of these options, that somehow we immediately go to how do you reward for quality, and that the quality parameters right now go to things like network adequacy, and I've always had a problem with that. I just feel like for hospitals, for nursing homes, for facilities, we have a basic level of standard of quality that is articulated, but we don't for these large

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delivery systems. So I start with that.

I started thinking is there an alternative to bonuses that went more along the lines of if you don't meet basic standards for the parameters we've laid out, then you will be disenrolled or terminated after a period of, say, three years or two years of not performing up to standard. In other words, how do we raise the average instead of just rewarding the top performers? So I'm sympathetic to where Paul's kind of devil's advocate position was.

And then on Pat's point -- oh, and related to that is I think that disclosure is where we really ought to be focusing rather than really looking at the bonus system per se. I realize we're going to look at that, but I think it's the consumer behavior and what does it take to crack that code of getting beneficiaries to begin to really look at some of these comparisons. And I think the literature is pretty dismal that beneficiaries don't tend to compare for quality.

So the question I have is: What will it take? How will we get to them? And I think that's clearly important, not how do we reward those that seem to perform above some sort of standard that we set.

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On Pat's point with the CAHPS survey, I think if you go to more of a disclosure emphasis of consumer education, then CAHPS has a role to play. But it's not actually, you know, affecting, if you will, the rating per se up or down, but it gives information the way you go to Amazon and you look at consumer reviews of products that you're considering buying. So I think it could be put in better perspective in that way.

I worry about if CAHPS takes too big a role, as she was saying, that you create a downward spiral, that unless risk adjustment is really good, you're going to create a situation where the plans that get the lower contribution are the ones who need the higher contribution because they're dealing with a more difficult population or a population where access to providers is just not that good.

So, you know, I think we have to worry about what happens -- what are the unintended consequences of pushing too hard in one direction? So I would just say that's important.

So back to the list, generally I like the idea of the government contribution and using auto-enrollment, but,

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again, it's with all these caveats of can it be done well and is it even the right direction to go. So I think those are good concepts. I like the fact that they actually are real rewards and may actually stimulate some behavior, at least among the well-performing plans or the plans capable of performing well under those parameters.

I agree it should be budget neutral. I would like us to think about whether there are other rewards or penalties, greater flexibility from a regulatory standpoint. Are there things that well-performing plans could do better, particularly if they deal with difficult populations, if they had greater flexibility than the government is now allowing? So what are some other things other than these, which I think are really good, that might be very appealing in this kind of environment?

But I'd just ask us to think about getting out of the mindset of quality bonuses is the way to go with a lot of this, because I think there should be a threshold of quality and we shouldn't juts rely on bonuses to achieve that.

MS. BRICKER: So I, too, concur with the majority of the conversation and wanted to touch just really on two

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points, one around budget neutrality.

On Slide 8, there's a reference to, you know, the fee-for-service benchmark and then if a plan were to meet or exceed, they receive payment. Is it possible in an ideal scenario where all plans breach this benchmark and receive bonus? So we've got to think about it Dodd-Frankly, I think, either force ranking them, the top 10 percent -- I'm making this up, but, you know, only a certain percentage of them would receive payment, and if none do, not so much that it's budget neutral but budget positive. You know, again, getting away from -- I think to maybe it was Paul's point, it may have run its course, and I'm not sure that continuing to throw money at it with respect to bonus payment is necessarily the way we should be thinking about it.

Secondly, on satisfaction, you see this, if you've ever shopped for a car, right? It's like the expert and then the consumer review. You got to Edmunds or something, there's two different kind of rating systems that you can consider -- people that are just complaining about the fact that they couldn't get their oil changed versus the expert saying, you know, it's a great car. So I

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think people do think about both an experience and kind of the expert's position when shopping, and I think we do have to -- we are in a world now where, you know, we're direct to consumer, and the consumer is looking online for where should I be putting my dollars. And if it's not the patient because maybe they're not as savvy, it is their caregiver that is doing the research and saying, you know, mom or dad or child, this is -- I'm reading about this and I'm concerned.

So I think that we do need to appreciate that the world has turned to something that is reliant upon experience and looking for kind of, you know, direction, and if not today, certainly in the next five, six years, the evidence shows that we're heading in that direction. So I think we have to build an infrastructure to appreciate that as people are making decisions directly and not, you know, just relying on, well, I've always gone to Dr. So-and-so so I will continue to do so.

Thanks.

DR. CROSSON: Rita.

DR. REDBERG: So I wanted to talk more about the measures and in particular the relationship between process

and outcome because I think it's interesting. We're all, I think, here because we're concerned that we want good outcomes for Medicare beneficiaries, but I guess what I got from your points was that -- and I think it's true -- a lot of the outcome has to do with the 64 years before they got to Medicare. And if that's what we thought, then we would be focusing our measures on improving life, as you said, diet and exercise in those 64 years, which is certainly, I think, an excellent idea but probably not what we're going to work on at MedPAC.

And so I was thinking, Jon, when you were talking about process and high quality, I can think of very few process measures that really do have a tight correlation with outcomes, maybe beta blockers for myocardial infarction, and the rates on that are already way above 95 percent for everything. So I don't know that we're doing a lot more with -- but I am duly shocked to know, very excited about looking at low-value care because I think that is an area where there is a tight correlation between process and outcome because a lot of those measures really could be process measures, and to me, those are lose-lose measures. We're doing things that are making people worse

that they don't need, and it's costing a lot of money, and it's resulting in lower quality of life and sometimes in shortening life.

And, certainly, the examples that you included in the mailing materials, the cancer screening, there is a lot of cancer screening that shouldn't be happening in Medicare beneficiaries if you follow the U.S. Preventive Services Task Force, you know, PSA, which is not recommended, but it's still being covered by Medicare, mammography for women over 75. I mean, all of that is only leading to more adverse -- more procedures that aren't needed and clearly a negative correlation between those processes and outcomes, pre-operative testing.

I got a question from a colleague just a few days ago asking, saying, "One of my patients who is doing very well, stable coronary disease, was going to have some arthroscopic knee procedure," and do I think he would need another cath before the procedure. And he already has compromised kidney function. I said, "No, absolutely not," but people routinely are thinking that anyone with heart disease needs to have a lot of extra testing before having routine elective surgery. I think a low-value care measure

could go a long way to improving quality and lowering cost. So I am very enthusiastic about pursuing those, and I think as compared to a lot of our other measures, which are harder, those would be very easy to get out of administrative claims data.

So I just want to say that I strongly support that move. Thank you.

DR. CROSSON: Jack.

DR. HOADLEY: So I have been trying to think about these issues from sort of a beneficiary lens and thinking about where some of the potential pitfalls are, and it sort of took me back to what's the value of doing these quality measures. There clearly are a lot of values. I mean, a lot of the purposes of sending signals to plans, that these are an important thing. If we do create a measure on low-value care and put it out there, then plans are going to say, "Oh, I really better pay attention to that," and I think that's where the quality bonuses have seemingly played some role. Whether they've already accomplished that and whether we should move beyond that is a fair question.

Certainly, they send a lot of signals to policy-

makers. If you see that the plans out there are all failing on a particular measure, that is a signal that something needs to be done, that just having the measure wasn't enough. Certainly, a sense of where one particular plan is falling down is information that policy-makers and the broader community get.

Certainly, there's value in providing this information to beneficiaries. I think there's a lot of questions about how a beneficiary processes this information.

In the Part D world, where I know best, there is a lot of thought, and we've had a group of people I've been meeting with. We've had a lot of discussions on this, including people who are SHIP counselors and sort of work in that world, how are beneficiaries using it. And the consensus seems to be that it's kind of a tiebreaker thing. Once I looked at the cost, once I looked at access to pharmacies translated into the MA world, once I looked at the access to my doctors, what's the overall cost to me, premiums and out-of-pocket cost, then maybe the tiebreaker is among those that are relatively comparable in access to providers, access to pharmacies, access to drugs, costs.

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Then I'll pick the four-star plan over the three-star plan, but without those other things happening, I'm probably not doing that.

And so what we're talking about here is sort of -- so I think all those are good things. They work. Some ways, there are flaws. I think what we're moving is another step towards thinking about how to create -- what's the right way to work with rewarding and what's the right way to create the intersection with premium support, and I think that's where I start to have -- start to struggle with how to do this in a way that won't mess things up and worry about we're doing this in a premature way.

So, if we still have lots of issues about whether we think our quality measures are really capturing what's going on, if we start to say, okay, I'm going to make this plan less expensive based on a potentially fairly flawed quality measure and therefore a beneficiary who wants to pick the lower-quality plan, but the one that happens to have access to their providers or has other features they like, it's suddenly going to be paying more to get that plan simply because of those quality measures. I don't want to see us doing that unless I really have a pretty

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high level of confidence that those quality measures are really capturing what's important to us in evaluating the system and what's important to consumers as shoppers, and I think right now, that's problematic. And that's even if I'm picking among, say, MA plans, and then with all the other issues we've got in terms of how to measure fee-for-service and how to put that into the benchmark, you know, it just feels like we're a long ways from ready to do that.

On the auto-enrollment, I guess I think this isn't really -- we haven't really been set up to talk about where auto-enrollment should fit into the system. Right now, we're sort of just putting this in as if auto-enrollment is in the system, how would quality play into that. I mean, I think there's a bunch of bigger examples or bigger issues around sort of what's the right role for auto-enrollment.

Right now, we do it, as you've talked about, in Part D for low income, but then it's really just about protecting people's subsidies, making sure they're in a zero premium plan. And so there are no cost consequences. If I assign you the Plan A versus Plan B, it's going to be a zero premium either way. The dual demos, there's no cost

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consequences by putting you in a plan. We're either just trying to make sure you get into a plan, you don't stay out of the system, and maybe, depending on how a particular State does it, they're trying to put people in plans that have some kind of match with providers and other things or tilt them towards quality.

So, I mean, I certainly think there's a role -- and again, using the Part D as the example -- to think about whether once we're randomly -- right now, we're randomly assigning people among a set of plans that will be free to the consumer to let quality enter into that, again, if we think -- and I'm skeptical about whether our current star ratings in Part D would really be robust enough to do that. But if we can make them robust enough, then to tilt more people or say that if you're below a certain star, you don't get random assignment or auto-assignment, that might make sense.

I think in the world we're moving into in premium support, I try to think through what's -- so, if I'm going to auto-enroll people in a bunch of plans where we're not talking about fully subsidized enrollment, would I be auto-enrolling, you know, me into a plan that is going to cost

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me $40 a month and my brother into a plan that's going to cost $60 a month based on some kind of consideration around the quality scores? I think we really have to think about what does that mean in terms of the cost consequences to do that.

If we're talking about auto-assigning among a set of plans that are equal in cost or in a subsidized world where we're just talking about people who are subsidized to keep it free, that's a different situation than we're talking about a broader population where there's a whole lot of cost measures going on.

So I think those are some of the issues that I would see that we need to think about as we go forward on this.

DR. CROSSON: Okay. Alice.

DR. COOMBS: Yes. Thank you very much, and I, too, would like to thank David. This was one of the most inspiring discussions I have had -- I mean I've listened to, and the deliberation has been really refreshing, and I thank you for the extra effort and the vision that you've poured into that diagram.

DR. NERENZ: I spent hours and hours on it.

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[Laughter.]
DR. COOMBS: First of all, I work from the bottom up. In terms of plan capacity, I have some mixed feelings about that because, in our area, I've seen where the enrollment for a certain plan is scheduled to be in a place where it's inconvenient for most people. It's not on the bus line. It's in an inopportune place where you could predict the socioeconomic status of the people that are going to enroll in the open enrollment. And so the harsh reality is that I would like to look more at plan capacity and what is that capacity, i.e., are they at capacity because they have too many dialysis patients? Are they at capacity because they're just not taking any more patients, period?
So my question would be what does that look like, and if there's elements of selection in regional areas, then it's a problem because it speaks to other issues that I don't think we've addressed yet.
So auto-enrollment, I agree, but I also think that we should have -- there should be some element of choice and education in the process of the auto-enrollment, and so that the low income would have an access to maybe a

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tool set that would allow them to make decisions in the process of the auto-enrollment.
For instance, if you said these two plans were available and these are the scenarios for which you have a choice in terms of the people listed, the providers listed on each of the plans, do they fit into what you need to do to actually be compliant with the plans' requirements, because that's the other piece of it too.
So I think there's two things going on. When we think about the beneficiary, we also have to think about the plans and some of the requirements of the plan and how you get to the plan and the geography and things like that.
The budget neutrality, I had another thought, and it wasn't so much as -- well, I agree with overall budget neutrality, but I don't think there's a problem with having regional areas that have been high cost with dropping them so that that area in and of itself doesn't have to be budget neutral, because if you feel that there's one area that, say, Sue's area really needs help and they come out to be non-budget neutral when you add up all the pieces of the puzzle, if that's better quality for that area, I think that maybe that we should -- not a lot of Robin Hood, but

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overall some Robin Hood going on at the local level and then the budget neutrality on the larger scale.
I think I agree with everything everyone said, and I especially appreciate something that you said, Pat, about the CAHPS scores and the hospital when you have pain. When the patient has pain afterwards, you can do everything perfect, but your CAHPS scores are going to be in the bottom of the trash. And it could be the pain because of many reasons, but that skews your CAHPS scores in every other aspect. So you can be pretty good on most parts, and then you get to pain, and then your overall score is affected by pain. And so that lends itself to something that you can't control.
And one other thing I wanted to say about quality for the plans and how we use readmission rates, ED rates, and -- the plans may not be -- and something that David said, the plans may not be totally responsible for admission rates per se. We've taken the readmission rates, and we've put it in the plans 100 percent, just like we do with some of the other entities, like the hospital.
The hospital and the PACs, they have proportionality, a greater control over those things than

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the plans do. I don't know if we thought about it, actually assigning a proportionality to the contribution to some of the outcome measures that we're looking at, especially when it comes to things like readmission rates for hospitals. I don't know if we've ever talked about that, but I almost feel like after David's discussion today and looking at all the components that contribute to readmission rates, mortality, maybe there should be some kind of attribution to some of these things as we look at them.
DR. CROSSON: Well, Alice, you make an important point here, which is that the number and size of Vicodin prescriptions is not part of the patient experience measure that we would anticipate being valid. Thanks.
[Laughter.]
DR. CROSSON: Brian.
DR. DeBUSK: Thank you.
I get really excited about the idea of premium support and MA synchronization because I think it's one of those big powerful ideas that could fundamentally change the system. So I hope we keep doing the high-level design on that.

As far as the specifics here, I do think that the quality should affect the government contribution, and I do believe it should be budget neutral. I mean, I don't think one program, for example, MA, should be receiving positive-only bonuses and others be taking bonuses and penalties.

I also get excited about this idea of auto-enrollment, and I think the bigger idea there is driving the beneficiary to have some type of contact with the system, even if it's to declare their intent to stay in fee-for-service. I mean, could we do something? And this may be heresy, but could we do something as simple as building an extra $20 into the premium when someone ages into Medicare until they make contact with the system, even if it's to declare their intent to stay in fee-for-service? I think something that drives that initial contact would be beneficial.

Then, finally, I'd like to end on one point. I'm probably going to be the standards guy on this Commission for the next 6 years because I think everything needs to be standardized, and I know I'm oversimplifying this. But I would love to see the sum of the stars equal the star of the sums, and I know that's probably overly ambitious. But

I hope that there's a healthy undercurrent, particularly with the staff.

Anytime you see, for example, those CAHPS scores -- you know, we were talking about how we could make modest changes to those and have them synchronized across all three platforms. I think anytime that we get the opportunity to recommend a standard and just quietly push everything together, I hope we do that, even as we do the high-level plan design. So I could see it really as two different pushes, the high-level plan design, which could take years, but then this undercurrent of trying to drive everything toward a common standard, because, again, I am thoroughly convinced that a mediocre standard that's uniformly applied is much, much better than the best standard that we could develop in here that's just intermittently applied.

Thank you.

DR. CROSSON: Thank you.

Paul, last --

DR. GINSBURG: I have a couple of thoughts, as the comments have gone around.

I was thinking a lot more about auto-enrollment,

and I think in a premium support system, that could be very useful doing it by geographic area. So if in this geographic area, the Medicare Advantage plans in aggregate are either lower cost or lower value, if we want to integrate the quality in, then we would have an auto-enrollment process of which the beneficiaries can opt out of and stay in fee-for-service or they can even -- once this gets them going, they might choose another plan and actually stay in Medicare Advantage but actually make an active choice. And I think that could address a lot of the criticism of premium support about the people that never pay attention, that never make any choices. It's really going to be hard to do risk adjustments to reflect the fact that they're probably more expensive than average.

I also had a couple of thoughts about plan capacity, and I think that in any auto-enrollment process or even a choice, I think unlike the Part D space where the capacity of plans is probably not really a factor, I think in physician hospital benefits, the capacity is an issue obviously in the staff and group model plans, but even in the network plans that networks have capacity problems. And you don't want to overwhelm a network, which means that

people aren't going to be able to get to see the physician in a timely basis.

So I think it's fairly simple, although Alice raised some very interesting dimensions that are really worth thinking about. Basically, at the beginning of the process, each plan says, "This is my capacity, X thousand enrollees," and to actually protect the plan from being overwhelmed. And, obviously, it would be we would have to think of the process. If there is excess demand for that plan, who gets it? Is it the people that just go through -- - presumably, the people who go through the enrollment process earlier get that, and that actually might be a motivation for people to get into the enrollment process.

And a final comment is that even though ACOs were very prominent in the paper and the presentation, they have had little mention in the discussion, and I think maybe this is a reflection of the fact that premium support is really about MA and fee-for-service, with ACOs a part of fee-for-service. If we actually evolve the ACOs in such a way that there was an affiliation or enrollment dimension, then we would have to -- but now it's just -- and, hopefully, ACOs will be successful long term and make the

fee-for-service world in general more successful, but I don't think we need to spend too much time speaking specifically about them now when we talk about premium support.

DR. CROSSON: Jon.

DR. CHRISTIANSON: I just wanted to comment on something Rita said because I think it's got some real potential. The outcome measures that we use for plans, they're really provider outcome measures that we attribute back to plans because we think plans have mechanisms to influence provider behavior, and we want to encourage them to use those mechanisms.

But I think with respect to the overuse, misuse, the strength of the mechanisms that plans have to influence provider behavior is much stronger because you say, "We're not paying," as opposed to "We'll give you a 5 percent bonus to increase this or that activity within a plan." So I think focusing some attention on those misuse measures makes a lot of sense because I think there's more leverage for plans, financial leverage, and therefore, we might be able to actually see some results.

DR. NERENZ: And also, just a friendly minute, on

that point, the causal network, I think, is also less complex, so that's another reason why.

DR. CROSSON: And plans also can exercise choice in terms of --

DR. CHRISTIANSON: Who the --

DR. CROSSON: Yeah, who is on the network from year to year.

Okay. Seeing no further comments, Ledia, Carlos, thank you very much. Nice job.

And we will move on to the next presentation.

Okay. For our final presentation and discussion for October we are going to, at the end of the summer, take another dive into the donut hole, a donut hole dive.

[Laughter.]

DR. CROSSON: Rachel and Shinobu, I just wanted to compliment you on the chapter. I do this all the time. I know it's getting boring but it's -- it was very clear, and also extremely readable and concise, and thank you for that.

So we're going to talk about the issue of biosimilars, evolving issue in Medicare Part D. And it looks like, Rachel, you're starting out?

DR. SCHMIDT: I am, yeah.

Good morning. Yesterday you discussed incentives behind Medicare's payments for Part B drugs, many of which are biological products. Today Shinobu and I are going to present information about biologics and their follow-on products, called biosimilars, within the context of Part D, Medicare's outpatient prescription drug benefit.

There are a number of biosimilars products that are beginning to enter the market. This is an introduction to the topic, thinking through the extent to which biosimilars might help to improve access to therapies and moderate growth in Part D spending in the way that generics have.

I'll provide background about biologics and biosimilars, and then we'll walk you through issues related to how the market entry of biosimilars could play out in Part D. We'll discuss recent use of and spending for biologics within Part D, factors that affect whether prescribers and patients begin to use biosimilars, and guidance that CMS has provided to Part D plans about biosimilars. Biosimilars are excluded from Part D's coverage-gap discount, and we will describe how that might

affect incentives for using biosimilars. Then we'll open things up for your discussion.

Most medicines are small-molecule drugs manufactured through chemical processes at relatively low cost. After a brand-name manufacturer has marketed their drug for a period of time, others can enter the market and produce what are nearly identical generic versions at much lower costs.

However, the biopharmaceutical industry has moved toward developing large-molecule biologics, which are more complex and are made from living organisms or tissues. A wide range of products fall under the term biologics including vaccines, insulin, and therapeutic proteins. They are used for conditions such as cancers, multiple sclerosis, and inflammatory diseases like rheumatoid arthritis. Biologics are typically injectable or infusible, and they often require special handling such as refrigeration.

The term "biosimilar" is used for follow-on products that have "no clinically meaningful differences" from a reference biologic in terms of safety, purity and potency. Biosimilars are like generics in the sense that

they can introduce price competition for the reference product. However, biosimilars are different from generic drugs in important ways. Because of their complexity, manufacturers of biosimilars cannot make exact duplicates of the reference product. Even a manufacturer of a reference product may see small changes in their product over time. Also, biosimilars are more expensive to develop and manufacture than generics. And unlike generics, the process for getting FDA approval of a biosimilar may involve clinical trials, which can be expensive.

Biologics and their biosimilars tend to be specialty drugs that have high prices. For example, some biologic medicines for multiple sclerosis may have cash prices at the pharmacy counter on the order of $6,000 for a one-month supply.

Relatively few individuals take biologics, but they account for a vastly disproportionate share of spending. One paper from 2015 estimated that nationwide, biologics made up 1 percent of all prescriptions filled but 28 percent of spending. IMS estimates that spending growth for biologics has outpaced spending for small-molecule drugs, and biologics' share of total drug spending has been

increasing.

Those trends raise concerns within the context of Medicare Part D. First, enrollees who take these medicines face high out-of-pocket costs, especially at the start of a benefit year before they reach the out-of-pocket threshold. And second, as more biologics are introduced and as their prices grow, that puts upward pressure on Part D program spending, and I'll elaborate on this in a minute.

Remember, Medicare Part D pays for biologics and biosimilars in a very different way than Part B. In D, Medicare doesn't pay a clinician to administer a drug. Part D covers biologics that are self-injectable and dispensed through an outpatient pharmacy, typically a specialty pharmacy. The patient must be an enrollee in a private Part D plan. That plan includes its estimate of the enrollee's annual spending for biologics as part of its bid -- of the bid it submits to Medicare for delivering all outpatient drug benefits. Medicare pays the plan a monthly capitated amount based on bids, and Medicare also pays for 80 percent of spending above Part D's out-of-pocket threshold through individual reinsurance. From the combination of Medicare's payments and enrollee premiums,

plans pay pharmacies rates they've negotiated with the pharmacy for the prescriptions their enrollees fill, and plans also negotiate with drug manufacturers for rebates.

Enrollees who use high-priced biologics tend to reach Part D's out-of-pocket threshold, often early in the year. After that, they pay 5 percent of the price, which can still be a lot of money. For example, above the catastrophic threshold, that $6,000 per month multiple sclerosis drug would cost $300 per month out-of-pocket. Medicare pays for 80 percent of the price for the remainder of the year, so the taxpayer is bearing most of the cost. Last April, the Commission recommended a package of changes to Part D that was intended to give plan sponsors greater incentives and tools to manage spending for high-cost enrollees.

In 2014, gross spending for biologics in Part D totaled more than $15 billion or about 13 percent out of a total of $121 billion. Between 2011 and 2014, biologics spending grew by an annual average of 31 percent, compared with 13 percent for total Part D spending.

The chart shows you the makeup of biologics spending in Part D by treatment category. You can see at

the top that insulin makes up the largest share, almost 60 percent in 2014. Insulin products have lower prices per prescription compared with other biologic treatments, but we have lots of enrollees on insulin. The other two largest categories of biologics spending are for multiple sclerosis, in yellow, and inflammatory diseases, in red, like rheumatoid arthritis. While these two categories have fewer patients taking the biologics, average prices for their prescriptions are much higher. Between 2011 and 2014, average prices for medications in the top three categories grew by 16 to 22 percent annually, reflecting price inflation and the move to newer products and newer delivery mechanisms such as auto-injection pens.

In Part D, we've seen that encouraging beneficiaries to switch to generic drugs can help control drug spending and expand access. When many generic manufacturers enter the market, prices of treatment can fall by 70 percent or so. However, analysts caution us not to expect as dramatic an effect from biosimilars. For example, in 2008, CBO estimated that prices for biologic treatments might fall by 20 to 40 percent, with different effects across treatment categories and over time. CBO

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expected use of these medicines to expand as prices went down, but they still expected some net savings from biosimilars.

Countries in the European Union have been using biosimilars for a decade. The effects of the market entry of biosimilars vary by country, but prices within some treatment classes have fallen by 20 to 30 percent, even northwards of 50 percent. The countries with the largest effects have different institutional approaches than we do. For example, in some countries these therapies are delivered in a hospital setting and they hold "winner take all" procurement competitions among biologic and biosimilar manufacturers. In other countries, individual prescribers have more influence over which drug is used. Studies suggest that the entry of biosimilars has a larger effect in countries with policies that encourage biosimilar use, such as by conducting effectiveness studies and then sharing the results with prescribers and patients.

In the U.S., for 2017, recently one major insurer and a large PBM separately announced that they're putting biosimilar products on their commercial formularies and excluding the reference biologics. This means that they're

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using the market entry of biosimilars to negotiate for bigger rebates and lower prices.

The effects of biosimilar competition are going to depend on the extent to which prescribers and patients begin to accept and use those products, and take-up will depend on a number of factors.

One factor that could affect acceptance of biosimilars is immunogenicity. Because biologics and biosimilars are large-molecule drugs, the human body may create antibodies to them, often with benign results, but sometimes with clinically very significant effects. The structure of a biologic is very sensitive to how it is manufactured, and in turn that could affect the propensity for an immune response. Some stakeholders are concerned that biosimilars may have more variants in immune response. But the same issue affects reference biologics. For example, the reference biologic that comes off the production line of a new facility is likely to be slightly different.

The law distinguishes between biosimilars and interchangeable biosimilars. FDA hasn't yet released guidance on how to demonstrate interchangeability, but the

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idea is that there is no difference in clinical result or higher safety risk if you were to switch a patient from the reference biologic to the biosimilar, or vice versa. Federal law says that pharmacies can automatically substitute interchangeable biosimilars without involving the prescriber. For small-molecule drugs, the big reason generic use expanded rapidly was that pharmacies can substitute a bioequivalent generic automatically. No biosimilars have been designated as interchangeable yet, but almost half the states have already passed laws about automatic substitution that go further than federal law. Some require the pharmacy to notify the prescriber and the patient before substituting a biosimilar.

Naming conventions could also affect take-up. The FDA supports adding a four-letter suffix to the nonproprietary name of a biosimilar to help identify the manufacturer and trace use of the product. However, the FTC, the Federal Trade Commission, says this approach isn't necessary and will encumber competition by causing prescribers to believe that the products have clinically meaningful differences.

Other key factors that will affect take-up are

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the relative prices and out-of-pocket costs to the payer and patient, and another set of factors are aspects of Part D law and regulation, which we'll cover over the next few slides.

MS. SUZUKI: The first area relates to CMS' formulary reviews.

Formulary is a key tool used by plan sponsors to manage enrollees' drug spending. Current CMS guidance does not treat a biosimilar and its reference product as distinct drugs for purposes of satisfying the requirement to cover two drugs per class. But they are considered as separate drugs for transition fills. That is, a transition supply for an enrollee taking a reference biologic has to be reference biologic, and the same holds true for an enrollee taking a biosimilar.

When a new, less expensive drug enters the market midyear, plan sponsors may want to add that new drug on the formulary during the benefit year. For small-molecule drugs, adding a new drug and removing the brand version is considered a routine maintenance change, but adding a biosimilar and removing the reference product is treated as a non-maintenance change, and that means those formulary

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changes would be more difficult, requiring case-by-case review by CMS and the plan's Pharmacy and Therapeutics Committee.

Another potential obstacle for biosimilar use in Part D is related to copays for low-income subsidy enrollees. In Part D, LIS copays are set in law -- a lower amount for generic or multi-source drug and a higher amount for brand-name drugs. The same brand copay amount applies to both biosimilars and reference biologics. So LIS enrollees would not have the financial incentive to choose a biosimilar even if it is on a tier with lower cost sharing. Partly because of this situation, the Commission recommended in its June 2016 report that the Congress modify LIS copayments to encourage the use of lower cost drugs, including biosimilars.

The last area relates to the coverage gap discount that brand manufacturers pay, including manufacturers of reference biologics, but not the manufacturers of biosimilars.

Currently, manufacturers of reference biologics provide a 50 percent discount in the coverage gap. Because of the gradual phase-out of the coverage gap, in the near

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term, that 50 percent discount lowers the effective coinsurance rate beneficiaries pay on reference biologics relative to biosimilars. Once the coverage gap is closed in 2020, the coinsurance rate will be 25 percent for both reference biologics and biosimilars.

But the 50 percent discount has another effect. Because it's treated as enrollees' own out-of-pocket spending to determine when he or she has reached the out-of-pocket threshold, an enrollee using a reference biologic would reach the out-of-pocket threshold more quickly, with lower out-of-pocket costs, compared to a similar enrollee using the biosimilar. This effect will continue even after 2020.

For plan sponsors, the gap discount lowers the costs of reference biologics, and because enrollees reach the out-of-pocket threshold more quickly, there's less spending in the coverage gap and more spending in the catastrophic phase of the benefit, and this could potentially result in situations where overall costs to the plans are lower when enrollees use the reference product rather than its biosimilar with lower prices, and I'll illustrate that with using a numeric example on the next

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slide.

This hypothetical example looks at the financial implications of using a reference biologic that costs $3,000 per month and a biosimilar that costs 15 percent less, or $2,550.

The first column shows the benefit structure in 2020, when coverage gap is fully phased out and Part D benefit covers 75 percent of the costs. For reference biologics, that benefit cost is split between plans and manufacturers. Plan pays 25 percent and manufacturers pay 50 percent in coverage gap discount. In comparison, plan liability is 75 percent for biosimilars. It's higher because they are not subject to the gap discount. So even though the biosimilar has the lower price, the plan would pay less for the reference biologic than for the biosimilar.

Finally, because the gap discount is counted as true out-of-pocket spending, $2,250 count as true out-of-pocket spending if an enrollee used the reference biologic, but only $638 if that enrollee used the biosimilar. This means that an enrollee will have shorter duration in the gap phase and reaches the catastrophic phase more quickly

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if he or she used the reference biologic, and this is the benefit phase where the plan liability is reduced to 15 percent because Medicare picks up 80 percent of the costs in reinsurance. So the use of reference biologics could mean lower costs for the plans relative to a biosimilar, and at the same time, higher reinsurance costs for Medicare and the taxpayers.

So the coverage gap discount and the price distortion it causes could leave plans with mixed incentives when deciding whether to include a biosimilar or its reference product on their formularies. Generally, plan sponsors want to encourage their enrollees to use lower-cost products such as biosimilars to keep premiums low. But as we just saw, there could be financial advantages to using reference biologics because of the way the gap discount is structured.

One way to eliminate this price distortion is to apply the gap discount to biosimilars. This would strengthen plan incentive to encourage the use of biosimilars. And as you may recall, the Commission's June 2016 recommendation would exclude the gap discount from true out-of-pocket spending.

So the application of gap discount to biosimilars would standardize the treatment of all drugs and biologics in the coverage gap and ensure plans' incentive to use lower-cost products, including biosimilars.

Here's a summary of what we discussed today.

Part D spending for biologics has been increasing rapidly, and given the pipeline, it is expected to continue to grow.

While some biologics offer significant improvements in treatment, their high prices raise concerns about beneficiary access and long-term financial sustainability of the Part D program.

To the extent that biosimilars have lower prices than their reference biologics, their market entry could help address these concerns. The key question would be how much take up would we see in Part D? Prescriber and patient acceptance would be an important factor, but just as important is Part D law and regulations that affect incentives faced by patients and the plan sponsors.

We'd be happy to answer any questions you may have. We would also like to get your feedback on the level of interest in further investigating formulary rules and

the coverage gap discount, or any other related issues.

With that, we are happy to answer any questions.

DR. CROSSON: Thank you, Rachel and Shinobu.

So we have the opportunity for clarifying questions.

DR. DeBUSK: Yes, on Slide 7 and in the mailer, there's a reference to the European experience and what they've done with biosimilars because they do appear to be significantly ahead of us. Have we dug into any best practices? Are there any things that we could learn from a specific country's experience with biosimilars?

DR. SCHMIDT: It's always a little bit difficult in these cross-country comparison because, you know, the way they operate is quite different from what we do.

In terms of just trying to get to lower prices, there are some countries that, as I mentioned, do kind of these "winner take all" approaches. They have these tender procurements, and there's direct competition between the reference product's manufacturer and the biosimilar manufacturer. And it's in those situations where you're seeing the greatest degree of price drop. And it's not always the biosimilar that's lowering its prices actually.

But in other countries where they may have, you know, partial tenders where prescribers still have a little more control over what exactly -- which product they choose, and even in there, there's some degree -- the entrance of biosimilars has led to somewhat lower prices. It seems like over time interest in using biosimilars has increased among prescribers as they become more comfortable seeing them prescribed. Sometimes it may be for naive patients just starting treatment as opposed to switching someone who's already on an established regimen.

So I'd say that the countries that are involved in trying to do more interchangeability studies, effectiveness studies, and then just putting that information out there for prescribers and patients to see, I think that's had an effect.

MR. PYENSON: Thank you very much. Excellent report. A question on page 3. There's a statement that biosimilars are more expensive to develop and produce, and just focusing on the production side of that, my understanding is that protein synthesis has become much, much cheaper each year, and I'm wondering if there are any indices for that from outside the pharmaceutical industry

that could be used as a reference to know how much more expensive are these products to manufacture. So just a question there.

DR. SCHMIDT: In terms of the development costs, they're, I think, clearly higher because of the issue of potentially needing to do clinical testing. In terms of manufacturing costs, I have not seen indices of the kind that you're mentioning. I've seen financial analyst reports that compare production costs, manufacturing costs for a reference biologic producer relative to biosimilar manufacturers. And I think you're right, the processes are becoming more standard. They're tending to use in some cases the same contract manufacturers, and prices do seem to be coming down. But I don't have good data to compare them to the production costs of generics.

MR. PYENSON: So but, for example, we're very close to seeing generic insulins, or perhaps there's generic insulins that are out already, and as a reference, insulin is perhaps as a standard point has been around for decades.

DR. CROSSON: I'm not sure what that was, a voice from somewhere.

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[Laughter.]
MS. BUTO: A disembodied voice.
MR. PYENSON: So maybe one point of reference could be what's happened to insulins and some of those that have come to the market.
Another question on page 6. Of course, insulins are a big dominant item here, and as you said in the note, that rebates aren't included here. Do you have any source of information? Could you come up with net-of-rebate estimates for this?
DR. SCHMIDT: Well, I have seen some approaches. We ourselves do not have access to the Part D rebate data except at the aggregate level, so we can't parse it out drug by drug, that sort of thing. But I know organizations like IMS have gone to SEC filings and the like and looked at revenues reported, if they can find it, you know, on a product level, and compared it to gross sales to try and get a stab at what the rebates might be. So I know guess using an approach like that would be a possibility.
MR. PYENSON: Thank you. One last question on page 7, to follow up on Brian's question on the European experience. One piece of evidence that might be useful in

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the discussion in the U.S. is where there was large-scale non-medical switching, whether there were increases in reports of adverse outcomes. And I don't know if that information is available or if it has been studied, so it's a question I have on the quality side.
DR. SCHMIDT: So, in general, we've heard that the European Medicines Agency hasn't pulled any products. You know, they've approved 21 biosimilars so far, I think, and they haven't pulled any because of safety issues that we know of. But we could look in more detail at some of those large procurement tender awards and switching to see if there's anything further on that.
MR. PYENSON: Thank you.
DR. CROSSON: Thank you.
MS. BUTO: On Slide 12, the one with the arrow which says "standardized treatment of all drugs and biologics in the coverage gap, ensure plan incentives to encourage the user of lower-cost products," did we recommend -- I cannot remember -- in the June report that generic manufacturers also provide the 50 percent discount? Is that what you're recommending here, or in addition to biosimilar manufacturers?

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MS. SUZUKI: Generic was not part of the recommendation, and here we're just repeating sort of along the lines of the example that we gave, applying the 50 percent discount --
MS. BUTO: To the biosimilar.
MS. SUZUKI: -- to the biosimilar, is what we --
MS. BUTO: Because I'm just wondering, particularly as some generic drugs are increasing in cost, whether that might be something that we want to think about.
And then the second one is I think we did talk about the difference between what Part D plans are paying for biologics versus our negotiated rates for biologics compared with Part B. But I can't remember what the difference was. Do you remember, ASP plus roughly -- do we have any idea in the aggregate? I know we don't have it drug by drug, but I thought we had some IMS data on that.
DR. SCHMIDT: I'm not familiar with that.
MS. BUTO: Okay.
DR. SCHMIDT: They tend to be different drugs for the most part. There's a little bit of overlap in some of the drugs, and I'm not remembering the comparison price.

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But we'll be happy to --
MS. BUTO: So they're different drugs, so it's Enbrel versus Remicade kind of thing.
DR. SCHMIDT: There's a small share for which there's coverage under B and D, but I'm not recalling --
MS. BUTO: It would just be interesting to know what kind of price discounts they're getting. Thank you.
DR. SCHMIDT: We'll have to get back to you.
DR. CROSSON: Clarifying questions?
DR. REDBERG: Thanks for an excellent chapter, and I think an important topic, and it's really going to be of increasing importance. And related to that, on page 2 of the mailing materials, you refer to over the next five years there's going to be more patent expirations for blockbuster biologics. Can you tell us which ones to be looking for? And do you know if there are biosimilars that are in the works for those?
DR. SCHMIDT: So in Table 2 in the mailing materials, we had some examples of things that are coming off patent, and in that table are included Humira, Enbrel, Lantus, NovoLog, NovoMix, Avonex, Rebif, some of the MS drugs. Those are the ones that fall under Part D. But

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there are other documents we could show you that refer to Part B drugs that are also likely to come off patent over the next five years.

DR. REDBERG: Thanks. And do you know if there are biosimilars?

DR. SCHMIDT: If you refer over to the table -- there are in many cases biosimilars, either recently approved or in the pipeline for most of these things.

DR. REDBERG: Thank you. Now I see it.

DR. CROSSON: Okay. I think we'll proceed with the general discussion. If we can put on Slide 14, I'd just draw your attention to the sub-bullets under the second bullet. We do have a couple of issues on the table. One has got to do, again, with the issue of LIS incentives, and the second one has to do with the question of application of the discount to biosimilars within the coverage gap.

Jack, you're going to lead off the discussion.

DR. HOADLEY: So I did think about David's precedent, whether I should try to up the game, and I thought about some PowerPoint slides but --

[Laughter.]

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DR. HOADLEY: I think this was a really great paper, as Jay said earlier, and very clear. I know I learned a lot from it.

I think our goal in this topic is to figure out how we best take advantage of the market forces that are developing for these drugs that are offered by biosimilars. You know, on the small molecule drugs, we really have seen a lot of savings generate for Part D in particular by the generic availability in a lot of the major drug classes over the last decade, and the question is: Can we accomplish anything like that with the biologicals? The numbers you present suggest it won't be at the same level, even in the best of circumstances, most likely. But you've also suggested there are a lot of issues that need to be dealt with to even get to the point of achieving some of the available savings to capture the potential.

And I do think it's significant -- and you just referenced it a moment ago in the answer -- that there are some clear opportunities that are in the near term within insulin, with rheumatoid arthritis drugs, with multiple sclerosis drugs, so this is not anymore a hypothetical, which, you know, three, four, or five years ago we sort of

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talked about these issues in a more sort of hypothetical framework, and now I think, you know, we're really on the cusp of having the products available to do this.

And so the question is: What can we do? I think there's one set of issues that you raised in the paper -- and I think it's important to raise even though they're not issues where we have a particular voice, they're not Medicare policy, but I think it's important to continue to raise in this context, so that's the interchangeability standards. Obviously, you know, FDA we think may come out with those pretty soon, and we'll obviously want to take a look at sort of what the implications of those are, the naming conventions, the state prescribing laws and substitutions. Those are all going to be factors in setting the context in which Part D policy will have to operate.

But I do think that you've highlighted some good policies that give us a chance to supplement some of what we did in last year's recommendations, and I see the potential for getting to some recommendations this year. So the specific things you raised, the formulary rules, I think this is one where we need to think it through pretty

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clearly. The potential things to be comparable to what's done with standard generic drugs is to allow plans to do mid-year corrections without as many of the hoops as they would have to go through today. The hoops today -- and we talked a lot about this last year -- really mean that a plan can't do it mid-year for all practical purposes, or to do it they've got to go through enough hoops that often it just doesn't happen within the time frame.

And then, secondarily, to clarify whether or not the plans, as we've seen some evidence of on the commercial side, can simply replace the original biological with the biosimilar, and, you know, I think we need, A, to make sure we understand what the current CMS guidance allows -- you talked about in terms of the two-drug requirement, but in some of these classes there are multiple products, so exactly what is allowed, you know, even for a new year where we're no longer talking about mid-year adjustments.

And then I think we need to think through sort of what is the right policy. These are not identical drugs as they are in generics. Is it a different product for interchangeable versus simply biosimilar? And what sort of best protects the rights of patients and prescribers to get

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the right drug? And that might be by allowing mid-year changes, allowing the biosimilar to replace the original drug on a formulary. But as we've already talked about in other contexts, exceptions will be key. There will be patients who need the other products. And so if nothing else, we need to reemphasize the role of exceptions and some of the obstacles that we know about in doing that. So I think that's one that needs some more thought. I think the potential for savings by allowing plans to do some things could be pretty substantial

We also talked a little bit last year about potentials for plans to use two specialty tiers to be able to provide differential cost sharing, not just 33 percent or 25 percent of a lower base cost, which would create some differential, but actually to accentuate that differential by saying, you know, have the 25 percent for the original products and a tier that had, say, 15 percent for the biosimilars. And, again, not necessarily to mandate that, but to make sure plans might have the flexibility to do that. Again, something we need to work through the consequences of, but I think something that seems to me -- I've seen one analysis that was shared with me by a plan

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that suggested it could be really a win-win. By simply creating that differential, you could keep the current coinsurance level for the original drug, a lower one for the biosimilar, and the negotiating advantage would really pay for the difference for them, and so sort of everybody wins -- the taxpayer, the beneficiary, and the plan. So I think that's something at least to bring up.

The LIS cost-sharing differential, am I right that we did have that in last year's recommendation? So, again, if we're talking about a package of things, we can reference back to what we did, but that one at least we've covered.

And then I think on the coverage gap, I found it very fascinating, because I had not thought through the math essentially that the current system leaves us with, and I think that's really ripe for fixing. And I'm not even sure that needs all that extensive further analysis or conversation. We may need to all be convinced that it makes sense, but on the surface at least, it really does feel like it makes sense to make sure that the discount -- or the two kinds of drugs are treated the same. I mean, we could think about making sure we know exactly how we want

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to do it, but it would look like you would ask the biosimilar manufacturers to pay the same kind of discount, and that seems like the most straightforward way to do that. So, again, that strikes me as very sensible, and then obviously we already have some things from last year on the counting rules, and so that would all fall -- whatever is done for one category of these would be done for the other.

The only other two points I would mention that relate to that, one is thinking about sort of what happens once the coverage gap is phased out fully in 2020. I am still not sure whether there's clarity on what CMS' policy will be for cost-sharing tiers in what's now considered the gap phase, which will still be the gap phase in the sense from the point of view of the manufacturer discounts, but to the beneficiary will look like kind of one continuous phase where, on average, they're paying 25 percent. But I think there's an open question of whether tiered cost sharing will be spread into that phase, and that intersects with this question in the sense of if there were two specialty tiers with different cost sharing to make sure that that followed. And then how does that intersect with

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the manufacturer discount?

Which then raises my last point, which is an issue that I'm beginning to see more discussion of, which is the fact that a lot of the pricing in this field is based on rebates, but patients, beneficiaries, pay -- coinsurance is based on the pre-rebate price, and that does create some complicated incentives that don't work so well, and that may be something that might be worth trying to look more into. Is there a policy answer of how to share the value of that rebate back with the patient so the patient is not paying 25 percent or in the catastrophic phase -- and, obviously, if our recommendation is taken up and we cap the out-of-pocket spending, this partly goes away. But right now in the catastrophic pay is paying 5 percent of the gross price when the net price may be in some cases as much as 30, 40, 50 percent lower, and there actually are some scenarios where there's kind of some strange incentives going on for the plan or the PBM in terms of making formulary decisions. So that's something that I think is at least worth bringing up and maybe working through some math on and seeing what that looks like.

DR. CROSSON: Okay. Thank you, Jack.
So let me see hands for a discussion. I think we'll start over here. David.
DR. NERENZ: Thanks.
I did want to follow directly, Jack, on your point. In reading this, I didn't fully appreciate this issue of the gap, coverage gap phase-out in 2020. I'm wondering, either a question to you or to your folks. When that happens, how much of this coverage gap problem that we're looking at sort of goes away just by the phase-out?
I know the text mentioned that there is a feature of it that the manufacturer discount is still factored into an equation. But I'm wondering, is there some value in actually running an illustration, like the one that just flashed by, in a post-2020 period? Is that worth doing? I just don't know this well enough to know if that would matter.
MS. SUZUKI: So we were talking about this as of 2020, which would be true for all of the years, but 50 percent gap discount continues. CMS is going to track the spending that would have fallen into the gap phase to figure out how much the discount.

DR. NERENZ: So this is 2020 and beyond?
MS. SUZUKI: Mm-hmm.
DR. NERENZ: Okay, okay. Thank you. Sorry I missed that.
DR. MILLER: And your vocabulary is confusing because everybody keeps calling it the "gap discount" even though the gap is done at this point.
DR. NERENZ: Okay. Well, that's kind of what I want to get into is whether we were entering a distinctly different era on this in 2020 that --
MS. BUTO: [Speaking off microphone.]
DR. NERENZ: I understand. Okay.
DR. HOADLEY: But you also had in the paper -- I mean, there are additional complexities on this between now and 2020 that make some of the differential -- even exaggerates it, but the point is it doesn't go away, this part of it.
DR. NERENZ: So that would suggest -- I was about to say maybe there's part of this problem that just solves itself by time that we don't have to worry about, but if it doesn't solve itself by time, we could conceivably get into some broader discussions about this coverage gap issue,

with implications beyond just biosimilars. I just was trying to clarify what gets fixed by time and what doesn't.
DR. CROSSON: Rita.
DR. REDBERG: So I wanted to say I do support our previous recommendations to exclude the gap discount from true out-of-pocket spending and to apply the gap discount to biosimilars. I think your examples shows -- I mean, the current system is like designed -- and to me -- a very illogical way to try to protect high-priced reference drugs and discourage people from switching to biosimilars, and I don't think that's something that we want to continue to support.
I also wanted to just suggest the issue of the formularies, and I find it sort of disturbing to see all the States that are passing laws to make it harder to substitute biosimilars. I think that 10 -- or, actually, it was now 20 years ago when we were getting more generics, that big case with Synthroid and how the manufacturing tried to suppress the studies that were done to show that the generic levothyroxine was the same as the Synthroid that was a big -- and there's even more money at stake here. So I just think that we need to be careful to pay

attention to the science, and that when the FDA approves a biosimilar, that it is a biosimilar, and it can be substituted. And all of these -- kind of the more we can do to strengthen the ability of physicians to substitute biosimilars, I think the better off our beneficiaries in the program will be.
There's clearly a lot of opposition, and there's a lot of money, and there is going to be more money.
I'm also -- and this is a little out of our province, but we talked about last time that it's been very slow for FDA to approve biosimilars, and that has been another roadblock, again, out of our purview but some concern.
And the last thing, I couldn't find it, but I thought I read that unlike the chemicals, that biosimilars don't get that six -- the first one -- don't get six months exclusivity, and I don't know if that was something we wanted to address, to give another incentive for biosimilars coming on the market.
Thank you.
DR. CROSSON: Amy.
DR. BAICKER: So I, too, am in support of

applying the gap discount to biosimilars and leveling the playing field. Like Rita, very concerned about the States that are passing laws and passing guidance with respect to substitution, ability, and the requirements and the hoops that physicians have to jump through. It's quite concerning.

Also in support of allowing the formulary change midyear. Again, we make it so hard on Part D plans to follow best practices in the commercial market, and we handcuff their ability to, again, use those market forces, so absolutely in support of allowing midyear change.

This wasn't discussed in the chapter, and maybe there's time for us this year or next to talk about the ability for Part D plans to limit their specialty pharmacy network. When you're diagnosed with cancer, you probably don't go to your primary care physician. You probably seek out an oncologist, and not all pharmacies are created equal. And being able to narrow that network, being able to drive additional value, quality, and monetary value, I think that's something that we should also consider. I'd be interested in what you could find with respect to outcomes in the commercial market when considering the

ability to limit specialty pharmaceuticals to those that are specialized to dispense them.

Thanks.

DR. CROSSON: Thank you.

Hands on this side? Bruce.

MR. PYENSON: Thank you.

If we could go to -- first, before going to a slide, I want to pick up on an issue that Jack raised about -- that the presentation on Slide 11, I thought, was very useful and very informative, and that's on the coverage gap. But if we could go to that as a reference, because I do have a chart that I want to coach through now.

[Laughter.]

MR. PYENSON: And unlike Dave, I'm actually going to talk about what the column headings mean and the row headings mean.

Dave, I am picking up -- I am imitating you, and, Mark, I think others are going to do likewise in the future.

DR. MILLER: Oh, no, I see where this is going. Not happy.

MR. PYENSON: Yeah. Where this is going is a

rule against, I know. This is going to be a one-up.

DR. CROSSON: These are gone. These are gone. They're gone.

DR. MILLER: So we're going to take away your pens.

[Laughter.]

MR. PYENSON: So the focus here is on the coverage gap from -- but Medicare doesn't spend any money in the coverage gap for non-low-income subsidy people, other than through the direct subsidy.

So the growing area over Medicare spending, as the previous months' reports have shown, is the catastrophic zone, and I think expanding this kind of analysis to the catastrophic zone would be really, really very useful and also to have a hypothetical treatment of rebates and the impact they have on plan spend and government spend in the catastrophic zone.

So here's the hypothetical I am suggesting. Move the numbers around, but purely hypothetical numbers, there's a reference drug that costs $60,000 and gets a 50 percent rebate. There's another reference drug, Reference Drug B, with a $30,000 retail -- and that's this column --

and also a 50 percent rebate, and a biosimilar with a $30,000 discounted rebate, the discounted retail, and also 50 percent rebate. Similar to what you have here, we could simplify this. Assume that the patient doesn't have any other drug or has some nominal amount of drug. I think you can calculate the patient paid for each of those three, the plan pay for each of those three, and the government pay for each of those things, each of those three drugs. And then allocate the rebate.

It turns out that the portion of rebate that goes to the government retrospectively is calculated as the government's portion of the total spend across all the coverage zones. So that's a portion that's certainly under half, perhaps under 30 percent, under 20 percent. But I think we can use a standard figure there.

I think that would help identify some things I've heard that may explain why some plans prefer a higher price and a higher rebate to a lower price, and I think that has bearing on the incentives that the rebate allocation as well as 80 percent of government liability in the catastrophic zone. So I think that illustration, like this illustration, would shed light because whether it's

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biosimilar reference drug, those folks are in the catastrophic -- or many of them if they take more than one, one script.

So thank you.

DR. MILLER: And I think -- so your analytical point beyond the example -- and I think this is something we can do, right? Yeah. So I think this is something we can do. I think your analytical point is that you can think of behavior at the discount and what the beneficiary is facing and that type of thing, which is what we kind of came into the room in, and you're saying also there are some behaviors above the catastrophic cap and how the PBM looks at the price of the drug versus the rebates, and you'd like that fleshed out, if possible.

MR. PYENSON: Yes.

DR. MILLER: Got it. I think we could probably crank through the example.

DR. CROSSON: Kathy.

MS. BUTO: But doesn't that, in a sense, just reinforce the recommendations we made in the last report to really address that catastrophic part of the benefit to address some of those distortions, if you will?

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MR. PYENSON: For sure. I think the allocation of rebate is also potentially an issue that there might be some issue in understanding that as well.

MS. BUTO: Yeah. Okay.

DR. CROSSON: Excuse me. The allocation of rebate means what?

MS. BUTO: He's talking about allocating the -- essentially the CMS rules for how one allocates the rebates when they're reconciling payments.

DR. CROSSON: I see. Okay. Thank you.

MS. BUTO: Across the whole benefit.

Okay. I got a little off track, but just on this slide in particular, where it says "plan liability," if we're talking post 2020, isn't that really the additional government liability built into the plan payment, in a sense? Because the reason the gap goes away is the government is putting more money into it, correct?

DR. SCHMIDT: Right. The plan is now covering that.

MS. BUTO: Yeah.

DR. SCHMIDT: But there's still the 50 percent manufacturer discount.

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MS. BUTO: Oh, I know that, and I agree with and support extending that to biosimilars. I would also ask us to consider extending it to generic drugs because, particularly as some of those -- particularly where there are few manufacturers, the costs are rising. I know we don't have the same issue of having the beneficiary out-of-pocket be as --

DR. SCHMIDT: Can I ask on that, were you thinking of all generics or some above a certain price threshold?

MS. BUTO: It could be either. I just feel like, you know, that's an area we haven't really focused on, but it can be also a cost-increasing area that is not of this dimension, certainly.

The only other comment I would make is -- and I think, Jack, the point you were making about beneficiary copays and the way they are calculated and so on, that's across the board and not just with respect to biologics, but across the whole benefit.

DR. HOADLEY: That's right, across the board. It's just that it's more acute. I mean, the dollars --

MS. BUTO: Are higher with --

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DR. HOADLEY: -- are bigger with the biologics.

MS. BUTO: -- with biologics. So I would just make sure we're clear on that --

DR. HOADLEY: Absolutely.

MS. BUTO: -- because I think it's a really good point that we ought to look at in the context of the whole benefit.

DR. HOADLEY: Yes.

MS. BUTO: And then, lastly, the issue of some of the formulary rules, I feel like I can support the direction we're going in, but I also feel we ought to at least understand better what the interchangeability interpretation is from the FDA before we strongly recommend that the plans can essentially discontinue the reference biologic when a biosimilar comes on because until we know better what those rules are or definitions, they may not be interchangeable, in the eyes of the FDA at least. So I would just caution that that needs to be informed by whatever FDA comes up with.

DR. CROSSON: Okay. I think I have Craig next -- or I'm sorry. Bill, did you want -- go ahead.

DR. HALL: I very much agree with the direction

that we're moving in, and I guess one other suggestion is that because only 1 percent of the Medicare population is directly affected by pricing, it may not get as much attention as it would if it influenced 20 or 30 percent.

So I wonder if you can perhaps give us some more information at some point about the trajectory of new drug development. I know that will still be kind of vague, but with the increasing use in cancer and the increasing age of our Medicare population, it would be nice to see how quickly we're going to go into catastrophic limits in terms of Medicare budgeting. I think this is an area we really need to have some information on.

DR. CROSSON: Craig.

DR. SAMITT: So I also endorse the recommendations here and certainly think that the coverage gap discount should apply to biosimilars, and then that obviously translates into the manufacturer discounts being excluded for both biosimilars and biologics.

The one piece we didn't cover that I don't want to lose is the presentation highlights that the LIS copay amount for biosimilars and biologics is equal, and I think we should also reevaluate that and determine whether we

want to promote biosimilar use by creating differential copays, lower copays obviously for the biosimilars versus the biologics.

And then I, too, to Bill's point and Bruce's point -- I'm interested in knowing whether we believe that folks will reach catastrophic levels more quickly in the short order, and then all of these discussions become somewhat irrelevant. I know that this will potentially slow reaching catastrophic, but with the evolution of new drugs in the pipeline, will we find that many more beneficiaries are reaching catastrophic levels? And we need to come up with a solution there as well.

DR. CROSSON: Thank you.

Paul.

DR. GINSBURG: Yeah. I also want to say that I think this is a good area to work in. I think it's a somewhat easier area to work in than some others on some dimensions because we're talking in terms of fostering competition, which takes the ideological issues out. Obviously, there's still a very powerful stakeholder that will not be happy with this, but just given the enormous growth of spending on specialty drugs and biologics in

particular, this is becoming large enough, it's just something we have to pay attention to.

I think, like Bruce, much of the issue is going to be about treatment of prescriptions in the catastrophic range because these drugs get up to that range so quickly.

I did want to mention, if we're talking about applying a 50 percent discount to biosimilars and perhaps generics, we need to tailor that number because we're going to get into situations with biosimilars, but especially generics where the gross operating margins are a lot lower than the reference drugs and the single-source drugs, just because of the prices of single-source drugs are trying to get back the R&D. And R&D is a lower percentage for the other drugs.

I think in answer to Kathy on the generic drugs, I'm concerned that we don't get into a tail wagging the dog, taking some of the examples of generic drugs where there's very little competition, where there's been very opportunistic behavior on raising prices, and have that dictate a broad generic drug policy, because I think that in many of the generic areas and I think where a lot of the dollars are, there's pretty significant competition. And

we don't want to actually mess with that by basically forcing manufacturers to provide drugs to Medicare beneficiaries and take an operating loss on them.

A final comment is that I think that I'm really glad that the team took a look at the situations abroad. I think that there's some areas that it's hard to learn from other health care systems because of basic societal value differences, but often in nitty-gritty areas like hospital payments and perhaps payment for prescription drugs, there's really the issues are very similar. The cultures aren't that different. The politics aren't that different, and we can learn a lot.

DR. CROSSON: Thank you.

Other comments?

[No response.]

DR. CROSSON: Seeing none, Rachel, Shinobu, thank you very much again for an excellent paper and presentation.

We will now proceed to the public comment period. If there are any members of the public who would like to make a comment, please come to the microphone.

[No response.]

DR. CROSSON: Seeing none, we are adjourned until November. Thanks very much to all the Commissioners.

[Whereupon, at 11:05 a.m., the meeting was adjourned.]

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